IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO, EASTERN DIVISION

IN RE: OHIO EXECUTION PROTOCOL LITIGATION

This document relates to: All Plaintiffs

BENNIE ADAMS (Inmate # 560-125), STANLEY ADAMS (Inmate # 420-071), DAVID ALLEN (Inmate # 246-920), ABDUL AWKAL (Inmate # 267-328), TYRONE BALLEW (Inmate # 261-875), RICHARD BAYS (Inmate # 325-266), ROBERT BETHEL (Inmate # 455-970), MELVIN BONNELL (Inmate # 204-019), DAVID BRADEN (Inmate # 380-366), ROMELL BROOM (Inmate # 187-343), QUISI BRYAN (Inmate # 399-595), CEDRIC CARTER (Inmate # 262-433), SEAN CARTER (Inmate # 356-659), AUGUST CASSANO (Inmate # 145-242), DAVEL CHINN (Inmate # 214-241), DOUGLAS COLEY (Inmate # 361-444), JAMES T. CONWAY (Inmate # 457-203), JERONIQUE CUNNINGHAM (Inmate #428-ROLAND DAVIS (Inmate # 499-211), ARCHIE DIXON (Inmate # 325-702), JOHN DRUMMOND (Inmate # 462-868), PHILLIP ELMORE (Inmate # 458-539), GREGORY ESPARZA (Inmate # 179-450), ANGELO FEARS (Inmate # 352-193), STANLEY FITZPATRICK (Inmate # 419-ANTONIO SANCHEZ FRANKLIN (Inmate JAMES FRAZIER (Inmate # 497-904), CLARENCE FRY (Inmate # 510-923), LARRY GAPEN (Inmate # 413-724), DELANO HALE (Inmate # 490-551), GERALD HAND (Inmate # 449-014), JAMES HANNA (Inmate # 152-169),

Case No. 2:11-cv-1016

JUDGE GREGORY L. FROST

Magistrate Judge Michael R. Merz

THIRD AMENDED OMNIBUS COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF, ATTORNEY FEES AND COSTS OF SUIT PURSUANT TO 42 U.S.C. § 1983 AND OTHER RELATED CAUSES OF ACTION

JURY TRIAL REQUESTED FOR ALL CLAIMS SUBJECT TO JURY TRIAL

JEROME HENDERSON (Inmate # 186-271),
WARREN K. HENNESS (Inmate # 287-375),
DANNY HILL (Inmate # 189-528),
GENESIS HILL (Inmate # 250-830),
TIMOTHY HOFFNER (Inmate # 315-988),
GARY HUGHBANKS (Inmate # 362-032),
LAMONT HUNTER (Inmate # 559-366),
PERCY HUTTON (Inmate # 195-620),
AHMAD ISSA (Inmate # 364-585),
ANDRE JACKSON (Inmate # 203-859),
CLEVELAND JACKSON (Inmate # 429-
KAREEM JACKSON (Inmate # 354-156),
DONALD KETTERER (Inmate # 465-959),
JUAN KINLEY (Inmate # 239-789),
ANTHONY KIRKLAND, (Inmate # 626-
LAWRENCE LANDRUM (Inmate # 189-
JERRY LAWSON (Inmate # 203-188),
CARL LINDSEY (Inmate # 350-106),
CHARLES LORRAINE (Inmate # 194-013),
GREGORY LOTT (Inmate # 198547),
JOSE TRINIDAD LOZA (Inmate # 250-059),
RALPH LYNCH (Inmate # 382-728),
FREDDIE MCNEILL, JR. (Inmate # 309-
JONATHAN MONROE (Inmate # 383-816),
SAMUEL MORELAND (Inmate # 190-490),
FREDERICK MUNDT (Inmate # 486-456),
TYRONE NOLING (Inmate # 222-599),
JAMES O'NEAL (Inmate # 325-132),
GREGORY OSIE (Inmate # 628-383),
GARY OTTE (Inmate # 264-467),
KERRY PEREZ (Inmate # 509-017),
RON PHILLIPS (Inmate # 279-109),
MARK PICKENS (Inmate # 635-147),
WAYNE POWELL (Inmate # 559-624),
WALTER RAGLIN (Inmate # 338-114),
WILLIAM SAPP (Inmate # 337-278),
MICHAEL DEAN SCOTT (Inmate # 387-
BOBBY T. SHEPPARD (Inmate # 315-284),
DUANE SHORT (Inmate # 525-858),
GEORGE SKATZES (Inmate # 173-501),
DAVID SNEED (Inmate # 192-040),

WARREN SPIVEY (Inmate # 216-212),
JOHN DAVID STUMPF (Inmate # 181-258),
RAYMOND TIBBETTS (Inmate # 363-178),
JAMES TRIMBLE (Inmate # 494-014),
MICHAEL TURNER (Inmate # 438-811),
RAYMOND TWYFORD (Inmate # 275-069),
ROBERT VAN HOOK (Inmate # 186-347),
WARREN WADDY (Inmate # 199-737),
MICHAEL WEBB (Inmate # 246-589),
HERSIE WESSON (Inmate # 563-308),
ANDRE WILLIAMS (Inmate # 209-534),
ROBERT WILLIAMS (Inmate # 381-764),
JEFFREY WOGENSTAHL (Inmate # 269-
Chillicothe Correctional Institution,
15802 State Route 104
Chillicothe, Ohio 44601,

and

SIDDIQUE ABDULLAH HASAN (Inmate #
KEITH LAMAR (Inmate # 317-117),
EDWARD LANG (Inmate # 532-018),
JASON ROBB (Inmate # 308-919),
JAMES WERE (Inmate # 173-245),
Ohio State Penitentiary
878 Coitsville-Hubbard Road
Youngstown, Ohio 44505,

and

ALVA CAMPBELL (Inmate # 354-963),
KEVIN SCUDDER (Inmate # 209-848),
KENNETH SMITH (Inmate # 326-630),
Franklin Medical Center
P.O. Box 23658
Columbus, Ohio 43223

and

TIMOTHY DUNLAP (Idaho Department of
Idaho Maximum Security Institution
P.O. Box 51
Boise, ID 83634

Plaintiffs,

v.

JOHN KASICH, Governor,

Defendant,

GARY C. MOHR, Director,

Defendant,

DONALD MORGAN, Warden,

Defendant,

STEPHEN GRAY,

New Party Defendant,

EDWIN VOORHIES,

New Party Defendant,

RICHARD THEODORE,

New Party Defendant,

CHARLOTTE JENKINS, Warden,

New Party Defendant,

CHRISTOPHER LAROSE, Warden,

New Party Defendant,

CHARLES BRADLEY, Warden,

New Party Defendant,

UNNAMED AND ANONYMOUS EXECUTION TEAM MEMBERS,

Defendants,

UNKNOWN PHARMACIES #1-100,

Defendants,

UNKNOWN PHARMACISTS #1-100,

Defendants,

and

UNKNOWN DRUG SUPPLIERS #1-25

New Party Defendants

and

JOHN DOES #1-25

New Party Defendants.

Third Amended Omnibus Complaint for Injunctive and Declaratory Relief, Attorney Fees, and Costs of Suit Pursuant to 42 U.S.C. § 1983 and Other Related Causes of Action On Behalf of All Plaintiffs Individually

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Plaintiff, by and through counsel, hereby files this Third Amended Omnibus Complaint for Injunctive and Declaratory Relief, Attorney Fees, and Costs of Suit Pursuant to 42 U.S.C. § 1983 and other related causes of action against Defendants John Kasich, et al., (hereinafter the "Third Amended Omnibus Complaint").[1] Plaintiff alleges and avers as follows.[2]

NATURE OF THE ACTION

1. Plaintiff brings this action under 42 U.S.C. § 1983 for violations and threatened violations of his rights secured by the United States Constitution.
2. Plaintiff also asserts claims for violation of the federal Racketeer Influenced and Corrupt Organizations Act (RICO), § 18 U.S.C. § 1961 *et seq.*
3. Plaintiff also asserts claims under state law that form part of the same case or controversy as the federal claims.
4. As to his § 1983 claims, Plaintiff seeks equitable, injunctive, and declaratory relief, as well as attorney's fees and costs of suit.
5. As to his remaining federal or state law claims, Plaintiff seeks equitable, injunctive, and declaratory relief, as well as attorney's fees and costs of suit.

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[1] Citations or references to ECF docket numbers in this Third Amended Omnibus Complaint refer to the docket in *Cooey v. Kasich*, *Cooey v. Kasich*, Case No. 2:04-1156, or the docket in *In re Ohio Execution Protocol Litigation*, Case No. 2:11-1016, and will be designated as such.

[2] The defined term "Plaintiff" shall be used in the singular to refer to each and all inmates listed in the caption of this Third Amended Omnibus Complaint, unless otherwise specified as necessary for an individual inmate. Notwithstanding the collective use of the term Plaintiff, each inmate individually raises the following allegations and claims.

6. The federal constitutional claims in this Third Amended Omnibus Complaint, as raised against all Defendants including the new Defendants, are cognizable under 42 U.S.C. § 1983. *Baze v. Rees*, 553 U.S. 35 (2008); *Hill v. McDonough*, 547 U.S. 573 (2006); *Nelson v. Campbell*, 541 U.S. 637 (2004); *Adickes v. S. H. Kress & Co.*, 398 U.S. 144 (1970); *Lugar v. Edmondson Oil Co.*, 457 U.S. 922 (1982); *Dennis v. Sparks*, 449 U.S. 24 (1980).

JURISDICTION AND VENUE

7. This action arises under 42 U.S.C. § 1983 for violations of the First, Sixth, Eighth, Ninth, and Fourteenth Amendments of the United States Constitution, as well as provisions of federal statutory or common law. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1343 (civil rights violations and equitable relief under an act of Congress), 18 U.S.C. § 1964(c) (jurisdiction over civil RICO actions), 28 U.S.C. § 2201 (declaratory relief), and 28 U.S.C. § 2202 (preliminary and permanent injunctive relief).

8. This Court also has supplemental jurisdiction over RICO claims as well as state law claims under 28 U.S.C. § 1367 because they are so related to one or more claims in this action raised under 42 U.S.C. § 1983 for which this Court has original federal question jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

9. This Court has personal jurisdiction over Defendants as they are residents of the State of Ohio, and are presently located in the State of Ohio, or are elected or appointed officials of the State of Ohio or otherwise acting on behalf of the State of Ohio, or have sought

confidentiality and other protections under Ohio law concerning activities which are the subject of this action, or conduct business in the State of Ohio.

10. Venue is proper in this judicial district pursuant to 18 U.S.C. § 1965 (for RICO claims) and 28 U.S.C. § 1391 because this is where Defendants can be found and transact their affairs and because a substantial part of the events or omissions giving rise to the claims occurred in this District.

PARTIES

A. Plaintiffs

11. **Plaintiff Bennie Adams** is a United States citizen and a resident of the State of Ohio.

a. Adams is currently a death-sentenced inmate in the custody of DRC Defendants.

b. Adams is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #560-125.

c. Plaintiff Adams does not have a scheduled execution date.

12. **Plaintiff Stanley Adams** is a United States citizen and a resident of the State of Ohio.

a. Adams is currently a death-sentenced inmate in the custody of Defendants.

b. Adams is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #420-071.

c. Plaintiff Adams does not have a scheduled execution date.

13. **Plaintiff David Allen** is a United States citizen and a resident of the State of Ohio.

a. Allen is currently a death-sentenced inmate in the custody of Defendants.

b. Allen is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #246-920.

c. Plaintiff Allen does not have a scheduled execution date.

14. **Plaintiff Abdul Awkal** is a United States citizen and a resident of the State of Ohio.

a. Awkal is currently a death-sentenced inmate in the custody of Defendants.

b. Awkal is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #267-328.

a. Plaintiff Awkal's execution is stayed and preliminarily enjoined by order of this Court.

15. **Plaintiff Tyrone Ballew** is a United States citizen and a resident of the State of Ohio.

a. Ballew is currently a death-sentenced inmate in the custody of Defendants.

b. Ballew is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #261-875.

c. Plaintiff Ballew does not have a scheduled execution date.

16. **Plaintiff Richard Bays** is a United States citizen and a resident of the State of Ohio.

a. Bays is currently a death-sentenced inmate in the custody of Defendants.

b. Bays is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #325-266.

c. Plaintiff Bays does not have a scheduled execution date.

17. **Plaintiff Robert Bethel** is a United States citizen and a resident of the State of Ohio.

a. Bethel is currently a death-sentenced inmate in the custody of Defendants.

b. Bethel is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #455-970.

c. Plaintiff Bethel does not have a scheduled execution date.

18. **Plaintiff Melvin Bonnell** is a United States citizen and a resident of the State of Ohio.

a. Bonnell is currently a death-sentenced inmate in the custody of Defendants.

b. Bonnell is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #204-019.

c. Plaintiff Bonnell has a scheduled execution date of October 18, 2017.

19. **Plaintiff David Braden** is a United States citizen and a resident of the State of Ohio.

a. Braden is currently a death-sentenced inmate in the custody of Defendants.

b. Braden is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe

Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #380-366.

c. Plaintiff Braden does not have a scheduled execution date.

20. **Plaintiff Romell Broom** is a United States citizen and a resident of the State of Ohio.

a. Broom is currently a death-sentenced inmate in the custody of Defendants.

b. Broom is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #187-343.

c. Plaintiff Broom does not have a scheduled execution date.

21. **Plaintiff Quisi Bryan** is a United States citizen and a resident of the State of Ohio.

a. Bryan is currently a death-sentenced inmate in the custody of Defendants.

b. Bryan is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #399-595.

c. Plaintiff Bryan does not have a scheduled execution date.

22. **Plaintiff Alva Campbell** is a United States citizen and a resident of the State of Ohio.

a. Campbell is currently a death-sentenced inmate in the custody of Defendants.

b. Campbell is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Franklin Medical Center, 1990 Harmon Ave, Columbus, Ohio under Inmate #354-963.

c. Plaintiff Campbell has a scheduled execution date of March 23, 2016.

23. **Plaintiff Cedric Carter** is a United States citizen and a resident of the State of Ohio.

a. Carter is currently a death-sentenced inmate in the custody of Defendants.

b. Carter is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #262-433.

c. Plaintiff Carter does not have a scheduled execution date.

24. **Plaintiff Sean Carter** is a United States citizen and a resident of the State of Ohio.

a. Carter is currently a death-sentenced inmate in the custody of Defendants.

b. Carter is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #356-659.

c. Plaintiff Carter does not have a scheduled execution date.

25. **Plaintiff August Cassano** is a United States citizen and a resident of the State of Ohio.

a. Cassano is currently a death-sentenced inmate in the custody of Defendants.

b. Cassano is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #145-242.

c. Plaintiff Cassano does not have a scheduled execution date.

26. **Plaintiff Davel Chinn** is a United States citizen and a resident of the State of Ohio.

a. Chinn is currently a death-sentenced inmate in the custody of Defendants.

b. Chinn is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #214-241.

c. Plaintiff Chinn does not have a scheduled execution date.

27. **Plaintiff Douglas Coley** is a United States citizen and a resident of the State of Ohio.

a. Coley is currently a death-sentenced inmate in the custody of Defendants.

b. Coley is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #361-444.

c. Plaintiff Coley has a scheduled execution date of March 14, 2018.

28. **Plaintiff James T. Conway** is a United States citizen and a resident of the State of Ohio.

a. Conway is currently a death-sentenced inmate in the custody of Defendants.

b. Conway is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #457-203.

c. Plaintiff Conway does not have a scheduled execution date.

29. **Plaintiff Jeronique Cunningham** is a United States citizen and a resident of the State of Ohio.

a. Cunningham is currently a death-sentenced inmate in the custody of Defendants.

b. Cunningham is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #428-323.

c. Plaintiff Cunningham does not have a scheduled execution date.

30. **Plaintiff Roland Davis** is a United States citizen and a resident of the State of Ohio.

a. Davis is currently a death-sentenced inmate in the custody of Defendants.

b. Davis is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #499-211.

c. Plaintiff Davis does not have a scheduled execution date.

31. **Plaintiff Archie Dixon** is a United States citizen and a resident of the State of Ohio.

a. Dixon is currently a death-sentenced inmate in the custody of Defendants.

b. Dixon is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #325-702.

c. Plaintiff Dixon has a scheduled execution date of March 20, 2019.

32. **Plaintiff John Drummond** is a United States citizen and a resident of the State of Ohio.

a. Drummond is currently a death-sentenced inmate in the custody of Defendants.

b. Drummond is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe

Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #462-868.

c. Plaintiff Drummond does not have a scheduled execution date.

33. **Plaintiff Timothy Dunlap** is a United States citizen and a resident of the State of Idaho.

a. is currently under a death sentence ordered by an Ohio court following conviction and sentencing under Ohio law.

b. is also under a death sentence ordered by an Idaho court following conviction and sentencing under Idaho law, which death sentence preceded his Ohio death sentence, and thus he is in the custody of the State of Idaho Department of Correction ("IDRC").

c. is under the control and supervision of the Idaho Department of Rehabilitation and Correction ("IDRC"), who have him incarcerated at the Idaho Maximum Security Institution, 13400 South Pleasant Valley Road, Kuna, Idaho 83634 under IDRC Inmate #35385.

d. Plaintiff does not have a scheduled execution date in Ohio.

34. **Plaintiff Phillip Elmore** is a United States citizen and a resident of the State of Ohio.

a. Elmore is currently a death-sentenced inmate in the custody of Defendants.

b. Elmore is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #458-539.

c. Plaintiff Elmore does not have a scheduled execution date in Ohio.

35. **Plaintiff Gregory Esparza** is a United States citizen and a resident of the State of Ohio.

a. Esparza is currently a death-sentenced inmate in the custody of Defendants.

b. Esparza is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #179-450.

c. Plaintiff Esparza does not have a scheduled execution date in Ohio.

36. **Plaintiff Angelo Fears** is a United States citizen and a resident of the State of Ohio.

a. Fears is currently a death-sentenced inmate in the custody of Defendants.

b. Fears is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #352-193.

c. Plaintiff Fears has a scheduled execution date of May 18, 2016.

37. **Plaintiff Stanley Fitzpatrick** is a United States citizen and a resident of the State of Ohio.

a. Fitzpatrick is currently a death-sentenced inmate in the custody of Defendants.

b. Fitzpatrick is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #419-722.

c. Plaintiff Fitzpatrick has a scheduled execution date of May 30, 2018.

38. **Plaintiff Antonio Sanchez Franklin** is a United States citizen and a resident of the State of Ohio.

a. Franklin is currently a death-sentenced inmate in the custody of Defendants.

b. Franklin is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #363-374.

c. Plaintiff Franklin does not have a scheduled execution date.

39. **Plaintiff James Frazier** is a United States citizen and a resident of the State of Ohio.

a. Frazier is currently a death-sentenced inmate in the custody of Defendants.

b. Frazier is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #497-904.

c. Plaintiff Frazier does not have a scheduled execution date.

40. **Plaintiff Clarence Fry** is a United States citizen and a resident of the State of Ohio.

a. Fry is currently a death-sentenced inmate in the custody of Defendants.

b. Fry is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #510-923.

c. Plaintiff Fry does not have a scheduled execution date.

41. **Plaintiff Larry Gapen** is a United States citizen and a resident of the State of Ohio.

a. Gapen is currently a death-sentenced inmate in the custody of Defendants.

b. Gapen is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #413-724.

c. Plaintiff Gapen does not have a scheduled execution date.

42. **Plaintiff Delano Hale** is a United States citizen and a resident of the State of Ohio.

a. Hale is currently a death-sentenced inmate in the custody of Defendants.

b. Hale is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #490-551.

c. Plaintiff Hale does not have a scheduled execution date.

43. **Plaintiff Gerald Hand** is a United States citizen and a resident of the State of Ohio.

a. Hand is currently under a death sentence ordered by an Ohio court following conviction and sentencing under Ohio law.

b. Hand is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #449-014.

c. Plaintiff Hand does not have a scheduled execution date in Ohio.

44. **Plaintiff James Hanna** is a United States citizen and a resident of the State of Ohio.

a. Hanna is currently a death-sentenced inmate in the custody of Defendants.

b. Hanna is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #152-169.

c. Plaintiff Hanna has a scheduled execution date of January 12, 2017.

45. **Plaintiff Siddique Abdullah Hasan** is a United States citizen and a resident of the State of Ohio.

a. Hasan is currently a death-sentenced inmate in the custody of Defendants.

b. Hasan is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at , Ohio under Inmate #130-559.

c. Plaintiff Hasan does not have a scheduled execution date.

46. **Plaintiff Jerome Henderson** is a United States citizen and a resident of the State of Ohio.

a. Henderson is currently a death-sentenced inmate in the custody of Defendants.

b. Henderson is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #186-271.

c. Plaintiff Henderson does not have a scheduled execution date.

47. **Plaintiff Warren K. Henness** is a United States citizen and a resident of the State of Ohio.

a. Henness is currently a death-sentenced inmate in the custody of Defendants.

b. Henness is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #287-375.

c. Plaintiff Henness has a scheduled execution date of June 22, 2016.

48. **Plaintiff Danny Hill** is a United States citizen and a resident of the State of Ohio.

a. Hill is currently a death-sentenced inmate in the custody of Defendants.

b. Hill is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #189-528.

c. Plaintiff Hill does not have a scheduled execution date.

49. **Plaintiff Genesis Hill** is a United States citizen and a resident of the State of Ohio.

a. Hill is currently a death-sentenced inmate in the custody of Defendants.

b. Hill is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #250-830.

c. Plaintiff Hill does not have a scheduled execution date.

50. **Plaintiff Timothy Hoffner** is a United States citizen and a resident of the State of Ohio.

a. Hoffner is currently a death-sentenced inmate in the custody of Defendants.

b. Hoffner is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe

Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under under Inmate #315-988.

c. Plaintiff Hoffner has a scheduled execution date of May 29, 2019.

51. **Plaintiff Gary Hughbanks** is a United States citizen and a resident of the State of Ohio.

a. Hughbanks is currently a death-sentenced inmate in the custody of Defendants.

b. Hughbanks is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #362-032.

c. Plaintiff Hughbanks does not have a scheduled execution date.

52. **Plaintiff Lamont Hunter** is a United States citizen and a resident of the State of Ohio.

a. Hunter is currently a death-sentenced inmate in the custody of Defendants.

b. Hunter is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #559-366.

c. Plaintiff Hunter does not have a scheduled execution date.

53. **Plaintiff Percy Hutton** is a United States citizen and a resident of the State of Ohio.

a. Hutton is currently a death-sentenced inmate in the custody of Defendants.

b. Hutton is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #195-620.

c. Plaintiff Hutton does not have a scheduled execution date.

54. **Plaintiff Ahmad Issa** is a United States citizen and a resident of the State of Ohio.

a. Issa is currently a death-sentenced inmate in the custody of Defendants.

b. Issa is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #364-585.

c. Plaintiff Issa does not have a scheduled execution date.

55. **Plaintiff Andre Jackson** is a United States citizen and a resident of the State of Ohio.

a. Jackson is currently a death-sentenced inmate in the custody of Defendants.

b. Jackson is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #203-859.

c. Plaintiff Jackson does not have a scheduled execution date.

56. **Plaintiff Cleveland Jackson** is a United States citizen and a resident of the State of Ohio.

a. Jackson is currently a death-sentenced inmate in the custody of Defendants.

b. Jackson is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #429-404.

c. Plaintiff Jackson has a scheduled execution date of July 20, 201.

57. **Plaintiff Kareem Jackson** is a United States citizen and a resident of the State of Ohio.

a. Jackson is currently a death-sentenced inmate in the custody of Defendants.

b. Jackson is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #354-156.

c. Plaintiff Jackson has a scheduled execution date of September 21, 2016.

58. **Plaintiff Donald Ketterer** is a United States citizen and a resident of the State of Ohio.

a. Ketterer is currently a death-sentenced inmate in the custody of Defendants.

b. Ketterer is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #465-959.

c. Plaintiff Ketterer does not have a scheduled execution date.

59. **Plaintiff Juan Kinley** is a United States citizen and a resident of the State of Ohio.

a. Kinley is currently a death-sentenced inmate in the custody of Defendants.

b. Kinley is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #239-789.

c. Plaintiff Kinley does not have a scheduled execution date.

60. **Plaintiff Anthony Kirkland** is a United States citizen and a resident of the State of Ohio.

a. Kirkland is currently a death-sentenced inmate in the custody of DRC Defendants.

b. Kirkland is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #626-893.

c. Plaintiff Kirkland does not have a scheduled execution date.

61. **Plaintiff Keith LaMar** is a United States citizen and a resident of the State of Ohio.

a. LaMar is currently a death-sentenced inmate in the custody of Defendants.

b. LaMar is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at , Ohio under Inmate #317-117.

c. Plaintiff LaMar does not have a scheduled execution date.

62. **Plaintiff Lawrence Landrum** is a United States citizen and a resident of the State of Ohio.

a. Landrum is currently a death-sentenced inmate in the custody of Defendants.

b. Landrum is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #189-982.

c. Plaintiff Landrum does not have a scheduled execution date.

63. **Plaintiff Edward Lang** is a United States citizen and a resident of the State of Ohio.

a. Lang is currently a death-sentenced inmate in the custody of Defendants.

b. Lang is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at , Ohio under Inmate #532-018.

c. Plaintiff Lang does not have a scheduled execution date.

64. **Plaintiff Jerry Lawson** is a United States citizen and a resident of the State of Ohio.

a. Lawson is currently a death-sentenced inmate in the custody of Defendants.

b. Lawson is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #203-188.

c. Plaintiff Lawson does not have a scheduled execution date.

65. **Plaintiff Carl Lindsey** is a United States citizen and a resident of the State of Ohio.

a. Lindsey is currently a death-sentenced inmate in the custody of Defendants.

b. Lindsey is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #350-106.

c. Plaintiff Lindsey does not have a scheduled execution date.

66. **Plaintiff Charles Lorraine** is a United States citizen and a resident of the State of Ohio.

a. Lorraine is currently a death-sentenced inmate in the custody of Defendants.

b. Lorraine is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe

Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #194-013.

c. Plaintiff Lorraine's execution is stayed and preliminarily enjoined by order of this Court.

67. **Plaintiff Gregory Lott** is a United States citizen and a resident of the State of Ohio.

a. Lott is currently a death-sentenced inmate in the custody of Defendants.

b. Lott is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #198-547.

c. Plaintiff Lott has a scheduled execution date of April 20, 2016.

68. **Plaintiff Jose Trinidad Loza** is a United States citizen and a resident of the State of Ohio.

a. Loza is currently a death-sentenced inmate in the custody of Defendants.

b. Loza is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #250-059.

c. Plaintiff Loza does not have a scheduled execution date.

69. **Plaintiff Ralph Lynch** is a United States citizen and a resident of the State of Ohio.

a. Lynch is currently a death-sentenced inmate in the custody of Defendants.

b. Lynch is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe

Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #382-728.

c. Plaintiff Lynch does not have a scheduled execution date.

70. **Plaintiff Freddie McNeill, Jr.** is a United States citizen and a resident of the State of Ohio.

a. McNeill is currently a death-sentenced inmate in the custody of Defendants.

b. McNeill is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #309-673.

c. Plaintiff McNeill does not have a scheduled execution date.

71. **Plaintiff Jonathan Monroe** is a United States citizen and a resident of the State of Ohio.

a. Monroe is currently a death-sentenced inmate in the custody of Defendants.

b. Monroe is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #383-816.

c. Plaintiff Monroe does not have a scheduled execution date.

72. **Plaintiff Samuel Moreland** is a United States citizen and a resident of the State of Ohio.

a. Moreland is currently a death-sentenced inmate in the custody of Defendants.

b. Moreland is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe

Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #190-490.

c. Plaintiff Moreland does not have a scheduled execution date.

73. **Plaintiff Frederick Mundt** is a United States citizen and a resident of the State of Ohio.

a. Mundt is currently a death-sentenced inmate in the custody of Defendants.

b. Mundt is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #486-456.

c. Plaintiff Mundt does not have a scheduled execution date.

74. **Plaintiff Tyrone Noling** is a United States citizen and a resident of the State of Ohio.

a. Noling is currently a death-sentenced inmate in the custody of Defendants.

b. Noling is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #222-599.

c. Plaintiff Noling does not have a scheduled execution date.

75. **Plaintiff James O'Neal** is a United States citizen and a resident of the State of Ohio.

a. O'Neal is currently a death-sentenced inmate in the custody of Defendants.

b. O'Neal is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #325-132.

c. Plaintiff O'Neal has a scheduled execution date of October 10, 2018.

76. **Plaintiff Gregory Osie** is a United States citizen and a resident of the State of Ohio.

a. Osie is currently a death-sentenced inmate in the custody of DRC Defendants.

b. Osie is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #628-383.

c. Plaintiff Osie does not have a scheduled execution date.

77. **Plaintiff Gary Otte** is a United States citizen and a resident of the State of Ohio.

a. Otte is currently a death-sentenced inmate in the custody of Defendants.

b. Otte is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #264-467.

c. Plaintiff Otte has a scheduled execution date of March 15, 2017.

78. **Plaintiff Kerry Perez** is a United States citizen and a resident of the State of Ohio.

a. Perez is currently a death-sentenced inmate in the custody of Defendants.

b. Perez is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #509-017.

c. Plaintiff Perez does not have a scheduled execution date.

79. **Plaintiff Ron Phillips** is a United States citizen and a resident of the State of Ohio.

a. Phillips is currently a death-sentenced inmate in the custody of DRC Defendants.

b. Phillips is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate # 279-109.

c. Plaintiff Phillips has a scheduled execution date of January 21, 2016.

80. **Plaintiff Mark Pickens** is a United States citizen and a resident of the State of Ohio.

a. Pickens is currently a death-sentenced inmate in the custody of DRC Defendants.

b. Pickens is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #635-147.

c. Plaintiff Pickens does not have a scheduled execution date.

81. **Plaintiff Wayne Powell**is a United States citizen and a resident of the State of Ohio.

a. Powell is currently a death-sentenced inmate in the custody of DRC Defendants.

b. Powell is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate # 559-624.

c. Plaintiff Powell does not have a scheduled execution date.

82. **Plaintiff Walter Raglin** is a United States citizen and a resident of the State of Ohio.

a. Raglin is currently a death-sentenced inmate in the custody of Defendants.

b. Raglin is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #338-114.

c. Plaintiff Raglin does not have a scheduled execution date.

83. **Plaintiff Jason Robb** is a United States citizen and a resident of the State of Ohio.

a. Robb is currently a death-sentenced inmate in the custody of Defendants.

b. Robb is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at , Ohio under Inmate #308-919.

c. Plaintiff Robb does not have a scheduled execution date.

84. **Plaintiff William Sapp** is a United States citizen and a resident of the State of Ohio.

a. Sapp is currently a death-sentenced inmate in the custody of Defendants.

b. Sapp is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #337-278.

c. Plaintiff Sapp does not have a scheduled execution date.

85. **Plaintiff Michael Dean Scott** is a United States citizen and a resident of the State of Ohio.

a. Scott is currently a death-sentenced inmate in the custody of Defendants.

b. Scott is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe

Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #387-350.

c. Plaintiff Scott does not have a scheduled execution date.

86. **Plaintiff Kevin Scudder** is a United States citizen and a resident of the State of Ohio.

a. Scudder is currently a death-sentenced inmate in the custody of Defendants.

b. Scudder is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Franklin Medical Center, 1990 Harmon Ave, Columbus, Ohio under Inmate #209-848.

c. Plaintiff Scudder does not have a scheduled execution date.

87. **Plaintiff Bobby T. Sheppard** is a United States citizen and a resident of the State of Ohio.

a. Sheppard is currently a death-sentenced inmate in the custody of Defendants.

b. Sheppard is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #315-284.

c. Plaintiff Sheppard does not have a scheduled execution date.

88. **Plaintiff Duane Short** is a United States citizen and a resident of the State of Ohio.

a. Short is currently a death-sentenced inmate in the custody of Defendants.

b. Short is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #525-858.

c. Plaintiff Short does not have a scheduled execution date.

89. **Plaintiff George Skatzes** is a United States citizen and a resident of the State of Ohio.

a. Skatzes is currently a death-sentenced inmate in the custody of Defendants.

b. Skatzes is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #173-501.

c. Plaintiff Skatzes does not have a scheduled execution date.

90. **Plaintiff Kenneth Smith** is a United States citizen and a resident of the State of Ohio.

a. Smith is currently a death-sentenced inmate in the custody of Defendants.

b. Smith is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Franklin Medical Center, 1990 Harmon Ave, Columbus, Ohio under Inmate #326-630.

c. Plaintiff Smith's execution is stayed and preliminarily enjoined by order of this Court.

91. **Plaintiff David Sneed** is a United States citizen and a resident of the State of Ohio.

a. Sneed is currently a death-sentenced inmate in the custody of Defendants.

b. Sneed is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #192-040.

c. Plaintiff Sneed has a scheduled execution date of August 1, 2018.

92. **Plaintiff Warren Spivey** is a United States citizen and a resident of the State of Ohio.

a. Spivey is currently a death-sentenced inmate in the custody of Defendants.

b. Spivey is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #216-212.

c. Plaintiff Spivey does not have a scheduled execution date.

93. **Plaintiff John David Stumpf** is a United States citizen and a resident of the State of Ohio.

a. Stumpf is currently a death-sentenced inmate in the custody of Defendants.

b. Stumpf is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #181-258.

c. Plaintiff Stumpf has a scheduled execution date of January 3, 2018.

94. **Plaintiff Raymond Tibbetts** is a United States citizen and a resident of the State of Ohio.

a. Tibbetts is currently a death-sentenced inmate in the custody of Defendants.

b. Tibbetts is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #363-178.

c. Plaintiff Tibbetts has a scheduled execution date of February 19, 2016.

95. **Plaintiff James Trimble** is a United States citizen and a resident of the State of Ohio.

a. Trimble is currently a death-sentenced inmate in the custody of Defendants.

b. Trimble is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #494-014.

c. Plaintiff Trimble does not have a scheduled execution date.

96. **Plaintiff Michael Turner** is a United States citizen and a resident of the State of Ohio.

a. Turner is currently a death-sentenced inmate in the custody of Defendants.

b. Turner is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #438-811.

c. Plaintiff Turner does not have a scheduled execution date.

97. **Plaintiff Raymond Twyford** is a United States citizen and a resident of the State of Ohio.

a. Twyford is currently a death-sentenced inmate in the custody of Defendants.

b. Twyford is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #275-069.

c. Plaintiff Twyford does not have a scheduled execution date.

98. **Plaintiff Robert Van Hook** is a United States citizen and a resident of the State of Ohio.

a. Van Hook is currently a death-sentenced inmate in the custody of Defendants.

b. Van Hook is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #186-347.

c. Plaintiff Van Hook has a scheduled execution date of October 19, 2016.

99. **Plaintiff Warren Waddy** is a United States citizen and a resident of the State of Ohio.

a. Waddy is currently a death-sentenced inmate in the custody of Defendants.

b. Waddy is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #199-737.

c. Plaintiff Waddy does not have a scheduled execution date.

100. **Plaintiff Michael Webb** is a United States citizen and a resident of the State of Ohio.

a. Webb is currently a death-sentenced inmate in the custody of Defendants.

b. Webb is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #246-589.

c. Plaintiff Webb's execution is stayed and preliminarily enjoined by order of this Court.

101. **Plaintiff James Were** is a United States citizen and a resident of the State of Ohio.

a. Were is currently a death-sentenced inmate in the custody of Defendants.

b. Were is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at , Ohio under Inmate #173-245.

c. Plaintiff Were does not have a scheduled execution date.

102. **Plaintiff Hersie Wesson** is a United States citizen and a resident of the State of Ohio.

a. Wesson is currently a death-sentenced inmate in the custody of DRC Defendants.

b. Wesson is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #563-308.

c. Plaintiff Wesson does not have a scheduled execution date.

103. **Plaintiff Andre Williams** is a United States citizen and a resident of the State of Ohio.

a. Williams is currently a death-sentenced inmate in the custody of Defendants.

b. Williams is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #209-534.

c. Plaintiff Williams does not have a scheduled execution date.

104. **Plaintiff Robert Williams** is a United States citizen and a resident of the State of Ohio.

a. Williams is currently a death-sentenced inmate in the custody of Defendants.

b. Williams is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe

Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #381-764.

c. Plaintiff Williams does not have a scheduled execution date.

105. **Plaintiff Jeffrey Wogenstahl** is a United States citizen and a resident of the State of Ohio.

a. Wogenstahl is currently a death-sentenced inmate in the custody of Defendants.

b. Wogenstahl is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #269-357.

c. Plaintiff Wogenstahl has a scheduled execution date of November 16, 2016.

B. <u>Defendants</u>

106. **Defendant John Kasich** is the Governor of the State of Ohio and has been since on or about January 10, 2011. He is the final executive authority in the state, statutorily and constitutionally responsible for the execution of all death sentences in Ohio and the manner in which those sentences are executed. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.

107. **Defendant Gary C. Mohr** is the Director of the Ohio Department of Rehabilitation and Corrections ("DRC" or "ODRC"), a department of the State of Ohio that was created and is maintained pursuant to Ohio Revised Code § 5120. Defendant Mohr is charged with and authorized under Ohio Revised Code § 5120.01 to prescribe and direct the promulgation of rules and regulations for the DRC, including the rules and regulations for the conduct of prison operations and execution procedures. Director

Mohr (or his designee) also oversees all executions administered in Ohio. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.

108. **Defendant Stephen Gray** is Chief Counsel of DRC. Upon information and belief, Defendant Gray has been tasked with creating rules and regulations for the conduct of prison operations and execution procedures, including the DRC policy designated 01-COM-11. Upon information and belief, Defendant Gray has also been tasked with identifying sources of execution drugs for DRC to use in carrying out a lethal-injection execution and/or obtaining or facilitating DRC's acquisition of execution drugs. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.

109. **Defendant Donald Morgan** is Warden of the Southern Ohio Correctional Facility, a correctional institution of the DRC that was created and is maintained pursuant to Ohio Revised Code § 5120.05. SOCF is the prison where Ohio carries out its death sentences. Pursuant to Ohio Revised Code § 5120.38, Defendant Morgan, as the Warden of SOCF, is charged with management of SOCF and the oversight and conduct of operations at SOCF, including executions carried out there. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.

110. **Defendant Edwin Voorhies** is a Managing Director of Operations at DRC, and, upon information and belief, an individual to whom has been delegated responsibility related to carrying out executions in Ohio. Defendant Voorhies has also been identified as one to whom the Director delegates command authority as the Director's

"designee" for carrying out an execution. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.

111. **Defendant Richard Theodore** is a pharmacist employed by DRC and, upon information and belief, an individual to whom has been delegated responsibility for matters related to execution drugs. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.

112. **Defendant Charlotte Jenkins** is the Warden at Chillicothe Correctional Center, a correctional institution of the DRC that was created and is maintained pursuant to Ohio Revised Code § 5120.05. CCI is the prison where Ohio houses the majority of its death row inmates, including several Plaintiffs. Pursuant to Ohio Revised Code § 5120.38, Defendant Jenkins, as the Warden of CCI, is charged with management of CCI and the oversight and conduct of operations at CCI. Pursuant to DRC Policy 01-COM-11, Defendant Jenkins will be responsible for implementing some portions of the Execution Protocol before an inmate housed at CCI is transferred to SOCF the day before a scheduled execution. She is sued here in her official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.

113. **Defendant Christopher LaRose** is the Warden at Ohio State Penitentiary, a correctional institution of the DRC that was created and is maintained pursuant to Ohio Revised Code § 5120.05. OSP is a prison where Ohio houses some number of its death row inmates, including some Plaintiffs. Pursuant to Ohio Revised Code § 5120.38, Defendant LaRose, as the Warden of OSP, is charged with management of OSP and the oversight and conduct of operations at OSP. Pursuant to DRC Policy 01-COM-11, Defendant LaRose will be responsible for implementing some portions

of the Execution Protocol before an inmate housed at OSP is transferred to SOCF the day before a scheduled execution. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.

114. **Defendant Charles Bradley** is the Warden at Franklin Medical Center, a correctional institution of the DRC that was created and is maintained pursuant to Ohio Revised Code § 5120.05. FMC is a prison where Ohio houses some number of its death row inmates, including some Plaintiffs. Pursuant to Ohio Revised Code § 5120.38, Defendant Bradley, as the Warden of FMC, is charged with management of FMC and the oversight and conduct of operations at FMC. Pursuant to DRC Policy 01-COM-11, Defendant Bradley will be responsible for implementing some portions of the Execution Protocol before an inmate housed at FMC is transferred to SOCF the day before a scheduled execution. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.

115. **Defendants unnamed and anonymous execution team members** are individuals involved with administering Defendants' execution protocol, policies and procedures, and who are known to Defendants and have been previously identified by court order only by anonymous team member numbers. They are sued in their official capacities for the purpose of obtaining equitable, declaratory and injunctive relief.

116. For ease of reference herein, Defendants Kasich, Mohr, Gray, Morgan, Voorhies, Theodore, Jenkins, LaRose, Bradley, and unnamed and anonymous execution team members are hereinafter called the "**DRC Defendants**."

117. Each of the DRC Defendants, at all times relevant hereto, are acting in their respective official capacities and under the color and authority of state law with respect to all acts described herein.

118. **Defendants Unknown Pharmacies #1-100** are partnerships, corporations or other business entities organized and existing under the laws of the State of Ohio, or some other state of the United States of America, or some foreign jurisdiction that are in the business of practice of pharmacy, and that are assisting DRC, either directly or through intermediaries, with obtaining drugs for the purposes of carrying out executions by lethal injection.

119. Plaintiff cannot discover the names of Defendants Unknown Pharmacies #1-100 because their identity and location are unknown at this time. Plaintiff is informed and has reason to believe that Defendants Unknown Pharmacies #1-100 are legally responsible, negligently or in some other actionable manner, for the events and occurrences described in this Third Amended Omnibus Complaint. The true names and capacities of Defendants Unknown Pharmacies #1-100 are unknown to Plaintiff at this time, although they are known to one or more DRC Defendants, and Plaintiff has, therefore, sued these unknown Defendants under fictitious names. When the true names and capacities of the Defendants Unknown Pharmacies #1-100 have been ascertained, Plaintiff will seek leave to amend this Complaint accordingly. Defendants Unknown Pharmacies # 1-100 are private persons or entities who are acting under the color of law, and they are sued for the purpose of obtaining equitable, declaratory and injunctive relief.

120. **Defendants Pharmacists #1-100** are individuals engaged in the practice of pharmacy and that are assisting DRC, either directly or through intermediaries, with obtaining drugs for the purposes of carrying out executions by lethal injection. Plaintiff cannot discover the names of Defendants Unknown Pharmacists #1-100 because their identity and location are unknown at this time. Plaintiff is informed and has reason to believe that Defendants Unknown Pharmacists #1-100 are legally responsible, negligently or in some other actionable manner, for the events and occurrences described in this Third Amended Omnibus Complaint. The true names and capacities of Defendants Unknown Pharmacists #1-100 are unknown to Plaintiff at this time, although they are known to one or more DRC Defendants, and Plaintiff has, therefore, sued these unknown Defendants under fictitious names. When the true names and capacities of the Defendants Unknown Pharmacists #1-100 have been ascertained, Plaintiff will seek leave to amend this Complaint accordingly. Defendants Unknown Pharmacists #1-100 are private persons who are acting under the color of law, and they are sued for the purpose of obtaining equitable, declaratory and injunctive relief.

121. **Defendants Drug Suppliers #1-25** are individuals, partnerships, corporations or other business entities organized and existing under the laws of the State of Ohio, or some other state of the United States of America, or some foreign jurisdiction engaged in manufacturing, procurement, transportation, import, export, sale (either retail or wholesale), supplying, or other distribution of drugs and that are assisting DRC, either directly or through intermediaries, with obtaining drugs for the purposes of carrying out executions by lethal injection.

122. Plaintiff cannot discover the names of Defendants Drug Suppliers #1-25 because their identity and location are unknown at this time. Plaintiff is informed and has reason to believe that Defendants Drug Suppliers # 1-25 are legally responsible, negligently or in some other actionable manner, for the events and occurrences described in this Third Amended Omnibus Complaint. The true names and capacities of Defendants Drug Suppliers #1-25 are unknown to Plaintiff at this time, although they are known to one or more DRC Defendants, and Plaintiff has, therefore, sued these unknown Defendants under fictitious names. When the true names and capacities of the Defendants Drug Suppliers #1-25 have been ascertained, Plaintiff will seek leave to amend this Complaint accordingly. Defendants Drug Suppliers # 1-25 are private persons or entities who are acting under the color of law, and they are sued for the purpose of obtaining equitable, declaratory and injunctive relief.

123. **Defendants John Does # 1-25** are individuals who are employed by or are associated with those Defendants Pharmacies #1-100 or Defendants Drug Suppliers # 1-25 who are not individuals. The true names and capacities of Defendants John Does # 1-25 are unknown to Plaintiff at this time, and Plaintiff has, therefore, sued these unknown Defendants under fictitious names. When the true names and capacities of the Defendants John Does # 1-25 have been ascertained, Plaintiff will seek leave to amend this Complaint accordingly.

124. For ease of reference herein, Defendants Pharmacies #1-100, Compounding Pharmacists #1-100, Drug Suppliers # 1-25, and Defendants John Does # 1-25 are hereinafter collectively called the **"Drug Source Defendants"** unless otherwise noted.

125. Each of the Drug Source Defendants, at all times relevant hereto, are acting under the color and authority of state law.

126. The DRC Defendants and the Drug Source Defendants are hereinafter collectively called "**Defendants**."

127. Upon information and belief, unless preliminarily and permanently enjoined, each of Defendants intends to act in their respective capacities and under the color and authority of state law to facilitate the execution of Plaintiff.

EXHAUSTION OF ADMINISTRATIVE REMEDIES

128. Pursuant to the Joint Stipulation filed on August 25, 2011 (*Cooey v. Kasich*, S.D. Ohio Case No. 04-1156, ECF No. 971), DRC Defendants have affirmatively and explicitly waived any exhaustion defenses.

JUSTICIABLE CASE OR CONTROVERSY

129. There is a real and justiciable case or controversy between the parties.

130. The DRC Defendants have promulgated their formal execution protocol as DRC Policy 01-COM-11, and they have adopted informal execution policies and procedures as well. The version of the DRC Defendants' formal execution protocol that is effective as of the filing of this Third Amended Omnibus Complaint was adopted effective June 29, 2015, and is hereinafter called "the 2015 Execution Protocol."

131. Upon information and belief, if Plaintiff's capital conviction or death sentence is not overturned in another judicial proceeding or through executive clemency, then Defendants will attempt to execute him.

132. It is the intention of Defendants, acting in concert with other state officials not named as defendants herein, to execute Plaintiff in the death house located on the grounds of the Southern Ohio Correctional Facility ("SOCF") in Lucasville, Ohio, which is operated and controlled by the DRC Defendants.

133. Absent judicial intervention, Plaintiff will be executed pursuant to Defendants' arbitrary and capricious lethal injection protocol, policies and procedures. There is a justiciable case or controversy regarding the unconstitutionality of Defendants' execution protocol, policies and procedures.

134. Plaintiff challenges the constitutionality of Defendants' lethal injection execution protocol and policies under 42 U.S.C. § 1983. This lawsuit does not challenge the fact of his conviction or his death sentence.

135. There is also a justiciable case or controversy regarding RICO claims under federal and state law, state-law claims against Drug Source Defendants, and Plaintiff's request for declaratory judgment under state law.

RELEVANT FACTS

136. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully stated herein.

137. Plaintiff is alleging constitutional violations based on Defendants' current Execution Protocol effective June 29, 2015; he is not alleging that Defendants can never execute him by any method.

A. Historical background

138. In 2002, the Ohio Legislature changed the State's manner of execution from electrocution to lethal injection.

139. At all times from 1994 to present, Ohio's statute governing lethal injection mandated that Defendants conduct a lethal injection execution such that it produces a "quick and painless" death.

140. DRC Defendants have previously conceded, during proceedings in this litigation on or about December 9, 2009, that a change in execution drugs is sufficient to restart a new statute of limitations period under *Cooey v. Strickland*, 479 F.3d 412 (6th Cir. 2007) ("*Cooey II*"), to raise lethal-injection method-of-execution challenges, and that they would not raise statute-of-limitations defenses in such situations.

141. Due to events overseen by this Court since the time of Plaintiff's most recently filed amendment (ECF No. 378, filed December 13, 2013), further amendment of Plaintiff's Complaint was deferred following Defendants' adoption of several new written execution protocols during that time period. In accordance with the Court's Orders issued July 8, 2015 (ECF No. 523, PageID 14180-81) and August 13, 2015 (ECF No. 527, PageID 14191-92), all claims herein, being brought at the first available opportunity after adoption of Defendants' new written execution protocol effective June 29, 2015 ("the 2015 Execution Protocol" or "the Execution Protocol"), are timely filed under any relevant statute of limitations standard. *See, e.g.*, *Cooey II*,

479 F.3d at 422, 424 (holding that the statute-of-limitations period for these claims can be reset when the lethal injection policy changes in a way that relates to the "core complaints"); *Cooey (Beuke) v. Strickland*, 604 F.3d 939, 942 (6th Cir. 2010) (explaining that "[g]iven the change in policy, the statute of limitations to challenge the new procedure began to run anew"). (*See also* Opinion and Order granting leave to file Second Amended Complaint by Plaintiff Phillips, ECF No. 356, PageID 10130, Oct. 31, 2013 (explaining that "Defendants' own conduct in adopting a substantively changed protocol necessitates amendment").)

142. Under authority set forth in the preceding paragraph, the DRC Defendants' adoption of the 2015 Execution Protocol restarts any applicable statute of limitations.

143. Within the previous two years, and thus within the shortest of any potentially applicable limitations periods, Defendants changed the "drugs required by [01-COM-11 which] shall be used," (DRC Policy 01-COM-11, ¶ V.2, p.3/19), when they added compounded execution drugs to the protocol, and when evidence surfaced that suggested Defendants intended to pursue imported execution drugs and were thus no longer planning to abide by a previous sworn statement by the Director of DRC that Defendants would "only use thiopental sodium that is pure, unadulterated, unexpired, not compounded, and in the sealed, original manufacturer's packaging." (*See Cooey*, ECF No. 817; *see also Cooey*, ECF No. 817-1, PageID 17564-65; *see also* ¶¶ 641-642 below.)

144. These and other recent changes to Defendants' written Execution Protocol, including the changes in organizational oversight and the drug-related changes increase the risk of harm to which Plaintiff will be subjected.

145. DRC Defendants' inclusion of compounded execution drugs as an option under the Execution Protocol is not simply a matter of swapping out one execution drug source for another. Involvement of compounded execution drugs directly involves a health care practitioner and the laws that govern that health care practitioner's behavior.

146. These and other recent changes to the Execution Protocol, new evidence of Defendants' involvement in facially illegal activity, as well as the facts and evidence related to executions during which compounded execution drugs were used, give rise to additional new claims that are raised herein at the first opportunity, and within any applicable statute-of-limitations period.

147. At all times relevant hereto, Ohio Revised Code § 2108.40 provided the legal definition of "death" under Ohio law: "An individual is dead if the individual has sustained either irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the brain, including the brain stem, as determined in accordance with accepted medical standards."

148. By changing their execution protocol with such frequency, by using drugs or combinations of drugs and doses that are unsupported by any scientific studies or data, and by contemplating the use of compounded execution drugs or unapproved drugs illegally imported from unreliable foreign manufacturers, Defendants are conducting experimental executions on each condemned inmate.

B. Defendants' formal execution protocol, DRC Policy 01-COM-11

149. DRC Defendants have designated DRC Policy 01-COM-11 as the DRC policy controlling human executions in Ohio.

150. Policy 01-COM-11 carries the force of Ohio administrative law.

151. Policy 01-COM-11 requires that all execution processes must be performed in a professional, humane, sensitive, and dignified manner.

152. Policy 01-COM-11 requires that the Execution Protocol must be applied in accordance with all applicable policies, administrative regulations, and statutes.

153. Since 2009, DRC Defendants have adopted a number of superseding written execution protocols designated Policy 01-COM-11, including versions of 01-COM-11 effective on the following dates: November 30, 2009; November 15, 2010; March 9, 2011; April 11, 2011; September 18, 2011; October 10, 2013; April 28, 2014; and January 9, 2015.

154. DRC Defendants adopted another superseding version of 01-COM-11, effective June 29, 2015 (the "2015 Execution Protocol"; throughout this Complaint, the use of the term "Execution Protocol" shall refer to the 2015 Execution Protocol unless otherwise identified). A true and correct copy of the Execution Protocol has been filed with the Court and can be found at ECF No. 521.

155. Administration of the Execution Protocol to a particular condemned inmate, like with other recent versions of 01-COM-11, begins approximately thirty days in advance of the scheduled execution date.

156. The Execution Protocol contains five "core" requirements, and deviation or variation from any number of those five core requirements throughout Defendants' administration of 01-COM-11 to a particular inmate is allegedly prohibited.

157. The core elements of the Execution Protocol (hereinafter the "Core Elements") are defined on page 3, Section V of the protocol (ECF No. 521-1, PageID 14162) and read as follows:

> 1. At least three Medical Team Members, two of whom are authorized to administer drugs under Ohio law, shall be used in the conduct of court-ordered executions.
>
> 2. The drugs required by this policy shall be used.
>
> 3. Functions required to be performed by medically-qualified persons, as described in this policy, shall be performed by Medical Team Members.
>
> 4. All Execution Team functions shall be performed by appropriately trained and qualified members of the Execution Team.
>
> 5. Only the Director can authorize a variation from the procedures stated in this policy but not a variation from the four requirements listed immediately above in subsection V.1.2.3. and 4. of this policy.

158. The Core Elements purport to provide necessary, core constitutional protections which, among other things, allegedly ensure that competent and properly trained actors are involved in key aspects of the execution process and that the work-product of those actors in key respects is subject to oversight, redundancies, and other built-in checks to eliminate mistakes and variations or deviations from the Execution Protocol's protections.

159. Strict compliance with the Core Elements is necessary for Defendants to carry out an execution that adequately protects the condemned inmate's constitutional rights.

160. An execution that is not administered in strict compliance with the Core Elements will subject Plaintiff to violations of his constitutional rights.

161. The Execution Protocol contains two possible drugs to be used, injected by peripheral IV injection, to execute a condemned inmate, hereinafter called Plan 1 (using pentobarbital) and Plan 2 (using thiopental sodium), described in more detail below.

162. The Execution Protocol contains no prohibition on using both pentobarbital and thiopental sodium during the course of the same execution.

163. Under Defendants' overarching execution policy and the Execution Protocol, and regardless of the lethal drug(s) to be used, a condemned inmate will be forced to lie down flat on his or her back for periods of time.

164. Upon entering the execution chamber, a condemned inmate will be strapped to the execution bed flat on his or her back, unable to move, with arms outstretched at each side.

165. The DRC Defendants will immobilize the condemned inmate by strapping him or her to the execution bed before the execution team begins attempted insertion of the peripheral IV catheters.

166. The DRC Defendants ensure that a condemned inmate lies flat on his or her back by employing "security team" members surrounding the inmate during efforts to establish IV access, and by strapping the inmate to the execution bed.

167. These security team and/or strap-down team members will physically ensure that an inmate remains flat on his back in a horizontal position throughout these procedures.

168. Although the DRC Defendants purportedly take only one to three minutes to establish peripheral IV access during execution rehearsals, successfully achieving peripheral IV access under the pressure and circumstances of a genuine execution has taken in the past and, upon information and belief, will take in the future, at least several minutes and may take half an hour or substantially more.

169. In the case of DRC Defendants' attempt to execute Romell Broom, some or all of the same DRC Defendant-medical team members who are expected to be on duty for

Plaintiff's attempted execution, were unable to successfully achieve and maintain peripheral IV access even after some two hours of trying.

170. During DRC Defendants' execution of Kenneth Biros, it took approximately 30 minutes for DRC Defendants to obtain peripheral IV access.

171. In the recent execution of Harry Mitts, Jr., the DRC Defendants required at least thirteen minutes to obtain peripheral IV access.

172. In the recent execution of Dennis McGuire, the DRC Defendants required at least ten minutes to obtain peripheral IV access.

173. Under DRC Defendants' overarching execution policy and the Execution Protocol, DRC Defendants will fill the IV tubing running from the equipment room to the inmate's IV catheter with saline solution before injecting the execution drug(s).

174. Under DRC Defendants' overarching execution policy and the Execution Protocol, DRC Defendants will inject the execution drug(s) into the IV tubing in the equipment room that is filled with saline solution. Thereafter a low-pressure saline drip will be used to purportedly "flush" the contents of the IV lines into the inmate.

175. The physical structures of DRC Defendants' execution chamber and the Equipment Room result in an extended length of IV tubing being used to inject the execution drug(s). Furthermore, that IV tubing will have a dip in the lines similar to an "s-trap" used in plumbing household sinks, in which some amount of the execution drug(s) will be trapped for some period of time during an execution.

176. Because of the volume of drugs involved, the length of the IV tubing and the traps in the IV lines, the execution drug(s) will be mixed with the saline solution already in

the IV tubing and the saline solution dripped into the lines after the plunger on Syringe 1 is emptied, before it reaches the condemned inmate.

177. Thus, DRC Defendants will be injecting the execution drug(s) into the condemned inmate at an inconsistent rate, and the drug(s) that the inmate will receive will be diluted by the saline solution.

178. Under accepted medical standards (Ohio Rev. Code § 2108.40), a simple absence of heart and lung sounds—which is all DRC Defendants assess—does not amount to irreversible cessation of circulatory and respiratory functions, or to irreversible cessation of all functions of the brain, including the brain stem.

179. Under accepted medical standards, visual monitoring and a stethoscope assessment of heart and lung sounds—which is all DRC Defendants do—is insufficient to determine whether an individual has sustained irreversible cessation of circulatory and breathing functions.

180. Under accepted medical standards, visual monitoring and a stethoscope assessment of heart and lung sounds—which is all DRC Defendants do—is insufficient to determine whether an individual has sustained irreversible cessation of all functions of the brain, including the brain stem.

181. DRC Defendants use only visual observations of the prisoner and a check of heart and lung sounds by stethoscope to declare death. DRC Defendants do not use any other monitoring instruments, devices, or methods that are necessary to determine death "in accordance with accepted medical standards" and Ohio law, Ohio Revised Code § 2108.40.

182. DRC Defendants are unable to declare death in accordance with Ohio law simply by watching the prisoner, or by listening for heart and lung sounds with a stethoscope.

183. Under the Execution Protocol and informal execution policies, Defendants do not do any of the following related to an execution, notwithstanding the events that occurred during previous problematic executions in Ohio and in other states:

a. use any vital-signs monitoring;

b. use pulse-oximetry (pulse-ox) monitoring;

c. have supplies of oxygen on hand in the Death House;

d. have resuscitative drugs, such as the reversal agent called flumazenil, on hand in the Death House;

e. have ventilation equipment such as ventilation bag, valve and mask, on hand in the Death House;

f. have intubation equipment on hand in the Death House;

g. have any way to maintain a patent airway and support of ventilation;

h. have any way to prepare and transport an inmate to an emergency health-care provider facility;

i. have any other resuscitative measures readily available and employable in the event that a problem arises during an execution or in the event that a stay of execution is issued after injection of the execution drugs;

j. train for any scenarios under which resuscitative measures would be necessary, or have any resuscitative plan of action at all.

184. If DRC Defendants attempt to execute him, Plaintiff intends to make a last statement before any such attempted execution.

185. DRC Defendants' overarching execution policy and the Execution Protocol lack any restraint on the number of attempts at peripheral IV access or the length of time those pokes, sticks, and stabs to the inmate can persist.

186. DRC Defendants are willing to engage in multiple, lengthy attempts at establishing and sustaining peripheral IV access.

187. DRC Defendants' policy and belief is that they are permitted to engage in efforts to complete an execution from the time the Warden reads the death warrant up to midnight of the same day, when the death warrant expires.

188. DRC Defendants' failure to have a time limit for attempting peripheral IV access places the team members in an increasingly stressful situation, rendering the team members unable to constitutionally administer an execution.

189. The inmate's physical and mental suffering is not explicitly included in the Execution Protocol's considerations for whether to halt further peripheral IV access attempts.

190. DRC Defendants' execution policy, including the Execution Protocol, fails to recognize that each inmate may present unique physical or psychological characteristics that may affect how a particular execution must be carried out while remaining within the bounds of the law.

191. DRC Defendants' execution rehearsals are not modified or tailored to address specific physical or psychological characteristics of any particular condemned inmate.

192. DRC Defendants have failed to prepare, train, or adjust the drug dosages to account for the unique issues any individual condemned inmate may present.

193. DRC Defendants' execution policy, including the Execution Protocol, fails to require a physician to personally supervise or monitor the preparation, administration or disposal of the lethal drug(s).

194. DRC Defendants' execution policy, including the Execution Protocol, fails to require a physician to personally insert a subclavian central line through which the lethal drug(s) may be injected.

195. DRC Defendants' execution policy, including the Execution Protocol, fails to require a physician or any other advanced-practitioner to be on hand to provide necessary medical care during the course of an execution attempt.

196. Other states require the use of physicians during the execution process.

197. DRC Defendants, during the previous failed attempt to execute Romell Broom, used a physician to participate in their unsuccessful efforts.

198. DRC Defendants' execution policy, including the Execution Protocol, fails to contain any provision by which Defendants are able to ensure that they do not violate constitutional prohibitions on executing an incompetent individual in violation of *Ford v. Wainwright*, 477 U.S. 399 (1986), and *Panetti v. Quarterman*, 551 U.S. 930 (2007).

199. DRC Defendants' execution policy, including the Execution Protocol, fails to contain any provision by which Defendants are able to ensure that they do not violate constitutional prohibitions established in *Atkins v. Virginia*, 536 U.S. 304 (2002), and reconfirmed in *Brumfield v. Cain*, 135 S. Ct. 2269, 192 L. Ed. 2d 356 (2015), on executing an inmate that is categorically ineligible for the death penalty due to his or her intellectual disability.

200. The 2015 Execution Protocol, as compared to the immediately preceding version which it superseded, made the following changes:

a. added "advanced level provider or registered nurse" to the types of persons who may be an Auxiliary Team Member;

b. added a person "who is currently certified or licensed within the United States as a registered nurse or nurse practitioner" as a possible Medical Team Member of the Execution Team;

c. added a requirement that any Auxiliary Team Member must attend at least one rehearsal per execution and that an Auxiliary Team Member shall not be required to attend an execution but may, at the Warden's discretion, attend an execution and provide consultation or advice to the Warden, the Director, and the Medical Team;

d. added SOCF's responsible pharmacist as a person the Warden may direct to order execution drugs;

e. added that the execution drugs may be ordered not just from a licensed pharmacist, but also, without an further qualification or limitation, "from a pharmacy, manufacturer, supplier or distributor";

f. added a paragraph stating that analytical tests for identity and potency "pursuant to the applicable USP/NF monograph" will be conducted on a sample from the batch of any compounded drugs to be used for execution; that a batch of compounded drugs will only be used if the sample "is properly identified as the intended drug and its tested potency is within the applicable monograph standard"; and that a sample of non-compounded execution drugs may also be tested for identity and potency "pursuant to the applicable monograph standard";

g. added a requirement that any Auxiliary Team Member must be given the training, at least once per year and prior to service, that Execution Team members receive on four specific topics;

h. increased the flexibility enjoyed by DRC in choosing the origin and nature of execution drugs by providing that the pentobarbital or thiopental sodium may be a drug "under whatever name it may be available from a *pharmacy*, manufacturer, *supplier*, distributor, *pharmacist*, or compounding pharmacy" (italicized entities added in the 2015 Execution Protocol);

i. provided that the execution drugs will be stocked within "an appropriate secured location," without any further definition of that term;

j. identified the "SOCF responsible pharmacist or another appropriately licensed pharmacist" as the persons who will distribute the execution drugs to the Drug Administrators on the day of an execution;

k. removed the requirement that "any lot number" of the execution drugs must be recorded, thereby removing a critical element of oversight.

201. The 2015 Execution Protocol is notable for what it lacks:

a. any analytical testing of execution drugs other than a provision stating that any compounded execution drugs will be tested solely for identity and potency, notwithstanding that analytical testing for matters such as sterility, purity, the presence of pyrogens and others are required by USP 797 and, therefore, now required under Ohio law and, accordingly, now required by Defendants' Execution Protocol;

b. any requirements or any point of reference for what constitutes a "sample from the batch" of execution drugs to be tested; whether such testing is even remotely relevant to the execution drugs to be used depends in part on the sample size and the batch size—for instance, will one vial in ten be tested? One vial in 1000?;

c. any provision limiting the source of any API to be compounded into drugs for an execution to an FDA-registered facility, or prohibiting the use of any API obtained on the grey or black markets;

d. any provision to ensure the API supply chain will be subject to inspection and mandatory documentation at each step in the supply chain to help assure that the raw API is not imported, is sterile, is unadulterated, is not contaminated with bacteria or fungus or any other substance, does not contain dangerous allergens or substances that may cause immediate anaphylactic reactions, or is otherwise anything other than pure, raw API for the execution drug in question;

e. any provision mandating pre-compounding analytical testing of the raw API to ensure the API is not imported, is sterile, is unadulterated, is not contaminated with bacteria or fungus or any other substance, does not contain dangerous allergens or substances that may cause immediate anaphylactic reactions, or is otherwise anything other than pure, raw API for the execution drug in question;

f. any provision for testing the pH level of the compounded drugs;

g. any provision for testing compounded drugs for purity and sterility, such as for the presence of pyrogens or other bacteria or fungus, allergens or substances that may cause immediate anaphylactic reaction, or other contaminants; testing for identity and potency will not properly identify whether additional substances are contained in the compounded drug;

h. any provision to preclude using compounded drugs that are incorrect concentration, or in any way misbranded or adulterated in any way other than identity or potency;

i. any provision regarding the requisite minimum qualifications of any compounding pharmacy and any compounding pharmacist to be used, or any provision setting out characteristics that would automatically disqualify a compounding pharmacy or a compounding pharmacist from performing any tasks related to execution drugs;

j. any provision regarding the requisite minimum qualifications for any analytical testing entity to be used, or any provision setting out characteristics that would

automatically disqualify a testing entity from performing any tasks related to execution drugs;

k. any requirement that any analytical testing of compounded execution drugs will even be done as a separate oversight step by an outside, independent laboratory; that is, there is nothing to preclude DRC from accepting any analytical testing performed by entities that are not truly independent from DRC, the Ohio Attorney General's Office or the local county prosecutor—such as the compounding pharmacy or pharmacist itself or Ohio's BCI crime lab—and which would, therefore, have a vested interest in a particular outcome of the analytical testing that undermines the credibility and reliability of any such testing;

l. any provision establishing the required testing protocols to be followed by any testing facility in conducting any analytical testing of execution drugs, or any provision requiring the testing facility in question to even have any written testing protocols for execution drugs at all;

m. any provision requiring creation of any documentation of analytical testing allegedly completed, or any provision requiring production of such documentation to any person or entity, let alone an independent expert, for independent verification of the validity of the testing protocol or the testing results;

n. any provision making matters related to analytical testing of compounded execution drugs a mandatory, "core" part of the Execution Protocols, thereby rendering it subject to deviation or variation on the whim of the Director or the Director's designee, whomever that happens to be at a given moment, if proceeding with an execution in strict compliance with the skeletal testing provisions in the protocol would be "difficult, impractical or impossible";

o. any provision requiring the compounder to adhere to current Good Manufacturing Practices ("cGMPs") for manufacturing the particular drug in question, or any provision requiring the compounder to verify that it is properly set up to compound high-risk sterile injectables;

p. any provision requiring mandatory inspection of the compounding pharmacy or outsourcing facility and the entity's operations;

q. any requirement that the compounding pharmacy, outsourcing facility, or compounding pharmacist be licensed by the Ohio State Board of Pharmacy or, indeed, by any state's pharmacy licensing entity;

r. any provision explicitly requiring adherence to the Beyond-Use Date limits for compounded drugs established under Ohio law;

s. any provision explicitly requiring adherence to the limits established under Ohio law on a pharmacy or pharmacist supplying more than a 72-hour supply of a compounded drug;

t. any provision explicitly requiring compliance with the United States Pharmacopeia chapter <797> as required by Ohio Admin. Code § 4729-16-03 for any compounded drugs used in executions;

u. any provision explicitly requiring compliance with section 503A of the Federal Food, Drug, and Cosmetic Act as required by Ohio Admin. Code § 4729-16-03 for any compounded drugs used in executions;

v. any provision establishing how compounded execution drugs will be transported, stored or otherwise maintained as required by the relevant state of the compounded drugs (frozen, refrigerated, or room temperature), or any provision mandating that compounded drugs be transported, stored or otherwise maintained as necessary depending on the relevant state of the compounded drugs;

w. any provision setting out how the Drug Administrators will prepare compounded execution drugs that are stored in a frozen or refrigerated state, such as when or how frozen compounded execution drugs will be thawed, which is significant because improper procedures such as premature thawing or thawing using inappropriate methods substantially increase the risk of harm from using compounded execution drugs;

x. any provision mandating any kind of analytical testing or any other form of verification of identity, identity, adulteration, contamination, pH level, sterility, and other similar concerns related to any execution drug that is imported, whether in bulk form as raw API or in manufactured form;

y. any provision explicitly prohibiting the use of any imported execution drug that was exported by a non-FDA-registered facility, or any provision explicitly prohibiting the use of any imported execution drug that comes from a grey or black market course, or any provision explicitly prohibiting the use of any drug that is an "unapproved drug" under federal law;

z. any provision explicitly mandating as a non-variable protocol requirement the full compliance by all relevant actors with all federal and state laws related to controlled substances, compounded drugs, imported drugs, pharmacy practice and other matters implicated by DRC's Execution Protocol;

aa. any provision explicitly prohibiting Defendants from using execution drugs that are obtained, imported, purchased, prescribed, possessed, dispensed, distributed, or administered (and any other terms of art under the federal CSA, federal FDCA or Ohio law) in violation of federal and state laws;

bb. any provision to explicitly ensure that the Warden's declaration of death of the condemned inmate is in accord with the point at which "death" occurs as defined and governed under Ohio law;

cc. any provision for use of any methods for assessing the inmate's awareness level, or any provision for use of any instrument—other than the implied use of a

stethoscope by the two persons who will listen to the inmate for heart and lung sounds—to help determine whether the inmate is truly dead as that term is defined under Ohio law;

dd. any provision for additional injections of the execution drug before a significant period of time—likely at least 5 or more minutes—has passed;

ee. any provision for explicitly ensuring emergency resuscitative equipment will be on hand in the Death House, or any provision establishing procedures for, or any Execution Team training for, implementing emergency resuscitative measures when cessation of the inmate's circulatory and respiratory system is still reversible after the Warden has called "time of death."

202. The absence of the above-recited necessary safety and other prophylactic measures related to analytical testing renders the analytical testing provision in the Execution Protocol insufficient to reduce the substantial risk of serious harm presented by using imported or compounded execution drugs.

203. The absence of the above-recited necessary safety and other prophylactic measures substantially increases the risk of serious harm to the inmate when DRC Defendants' Execution Protocol is applied to him.

204. DRC Defendants' execution policy, including the Execution Protocol, fails to contain relevant oversight or procedural protection provisions as to the Drug Source Defendants themselves, or sufficient oversight or procedural protection provisions as to the drug(s) the Drug Source Defendants provide for use in an execution pursuant to the Execution Protocol.

205. The Execution Protocol contains insufficient provisions by which DRC Defendants will ensure compliance with Core Element # 2, that all execution drugs to be used in a particular execution are, in fact, the specific execution drug type, quantity, concentration, sterility level, purity, origin, unadulterated, not misbranded, and

legally obtained, as required to be used by the Execution Protocol, making it highly likely that Defendants will deviate from Core Element # 2.

206. The Execution Protocol contains insufficient provisions by which DRC Defendants will ensure compliance with all applicable federal and state statutes and administrative regulations, thus making it highly likely that Defendants will deviate from Core Element # 2's requirements by using execution drugs that are not the drugs required to be used by the Execution Protocol because they are not legally manufactured, imported, compounded, distributed, dispensed, or otherwise provided to DRC Defendants.

207. The Execution Protocol, although providing that a sample of compounded execution drugs will be "analytically tested [for identity and potency] before they are used," contains no explicit mandate that any execution drugs procured from the Drug Source Defendants must be tested for purity, contamination, concentration, pH levels, sterility, adulteration, expiration/beyond its use date, improper storage or handling, or other factor that might affect an inmate's constitutional rights, making it highly likely that Plaintiff's constitutional rights will be violated through Defendants' use of compounded, imported, or otherwise-sourced execution drugs.

208. The Execution Protocol contains no explicit requirement for any inspections, quality-control verifications, licensure or background checks or any other verification of professional credentials, individual or professional character, qualifications, conflicts of interest, or anything else related to the Drug Source Defendants or facilities in which the Drug Source Defendants will manufacture, process, compound, package,

ship, import, store or hold or offer for sale execution drug(s), and as a result of a lack of oversight, serious complications are foreseeable and substantially likely.

1. Plan 1 of Defendants' Execution Protocol

209. Plan 1 of DRC Defendants' Execution Protocol requires the peripheral intravenous injection, via two syringes of 2.5 grams each of pentobarbital, 100 ml of a 50 mg/mL solution, for a total of 5 grams of pentobarbital, followed by a saline solution flush. In practice, DRC Defendants fill the IV tubing with saline solution before injecting the execution drug, and they inject a saline solution flush following each syringe.

210. Five additional grams of pentobarbital, 100 ml of a 50 mg/mL solution, are required to be obtained and kept available in the Equipment Room, to be drawn into two syringes and administered via peripheral IV injection if the primary five-gram dose of pentobarbital "proves to be insufficient for the procedure."

211. There is no provision in the Execution Protocol or DRC Defendants' informal execution policies for ensuring that additional quantities of pentobarbital are kept available in the Equipment Room to be used in an execution, and, upon information and belief, additional quantities of pentobarbital beyond 10 grams will not be present or available for DRC Defendants to use in an execution using Plan 1.

212. DRC Defendants contemplate using pentobarbital obtained under whatever name it may be available from Drug Source Defendants.

213. Use of pentobarbital in an execution carries a substantial risk of creating a paradoxical reaction, which occurs when a drug does not work as intended.

214. A paradoxical reaction to pentobarbital would cause an individual to remain hyper-aware as the execution proceeds. As a result of that heighted state of awareness, such

an individual would experience severe pain and needless suffering as the injected lethal drug does its work.

215. The risk of a paradoxical effect is even greater when the individual to whom the drug is being injected has suffered a brain injury, or has a history of aggression or impulsivity, a history of substance abuse, a history of psychiatric disorders, or characteristics that suggest PTSD.

216. Eyewitness and media accounts of executions in other jurisdictions using pentobarbital suggest that condemned inmates have experienced substantial pain, suffering and an extended duration of execution.

217. Upon information and belief, injection of five grams of pentobarbital via peripheral IV will not cause the condemned inmate to lose awareness for a period of minutes following the commencement of the injection.

218. Upon information and belief, injection of five grams of pentobarbital via peripheral IV will cause a condemned inmate to experience substantial pain while still aware.

219. DRC Defendants' own medical expert at the time, Dr. Mark Dershwitz, has presented testimony in this litigation admitting that pentobarbital can sometimes cause pain even when properly injected.

220. Using pentobarbital to kill in a lethal-injection execution creates a substantial likelihood the inmate will suffer a painful heart attack.

221. DRC Defendants know or should know that Plan 1 causes death by suffocation, unless death occurs by a painful heart attack.

222. Two injections of 2.5 grams of the pentobarbital in a 50 mg/mL solution will not act directly to stop Plaintiff's heart.

223. Two injections of 2.5 grams of the pentobarbital in a 50 mg/mL solution will suppress Plaintiff's breathing, creating a lack of oxygen to his heart.

224. The lack of oxygen caused by two injections of 2.5 grams of the pentobarbital in a 50 mg/mL solution will suppress the beating of Plaintiff's heart.

225. After two injections of 2.5 grams of pentobarbital in a 50 mg/mL solution have been completed, Plan 1 of the Execution Protocol calls for an Unnamed and Anonymous Execution Team Member ("Drug Administrator") to reenter the Execution Chamber to inspect the IV site for evidence of incontinence or infiltration and to listen to the prisoner for breathing and heart sounds. (DRC Policy 01-COMM-11, ECF No. 521-1, PageID 14174).

226. If the Drug Administrator does not hear any breathing or heart sounds, an "appropriate medical professional" (the County Coroner) shall evaluate the prisoner to confirm death.

227. Though Plan 1 of DRC Defendants' Execution Protocol does not define the phrase "evaluate the prisoner to confirm death," upon information and belief, by practice, the County Coroner listens to the prisoner for breathing and heart sounds.

228. Though Plan 1 of the Execution Protocol does not define the phrase "evaluate the prisoner to confirm death," upon information and belief, by practice, the County Coroner does not perform ECG or EEG examinations.

229. Though Plan 1 of the Execution Protocol does not define the phrase "sufficient time for death to have occurred," by practice, the Drug Administrator's evaluation and the County Coroner's evaluation both occur within approximately ten minutes following the two injections of 2.5 grams of pentobarbital.

230. Within approximately ten minutes after two injections of 2.5 grams of pentobarbital, Plaintiff's heart and breathing sounds will be undetectable.

231. Under Plan 1 of the Execution Protocol, after the County Coroner confirms death, Defendant Warden will declare Plaintiff dead by announcing a time of death. (DRC Policy 01-COMM-11, ECF No. 521-1, PageID 14175).

232. At the time Defendant Warden will declare Plaintiff dead by announcing a time of death, there is a substantial risk that Plaintiff will still have rhythmic electrical cardiac activity that can be detected through an ECG examination.

233. At the time Defendant Warden will declare Plaintiff dead by announcing a time of death, there is a substantial risk that Plaintiff will still have electrical activity in his brain that can be detected through an EEG examination.

234. Where the activity described in the preceding two paragraphs is present, Plaintiff is clinically and legally alive.

235. There is a substantial risk that Plaintiff's electrical cardiac activity and electrical brain activity will continue for as long as 45 minutes after breathing and heart sounds are undetected.

236. There is a substantial risk that Plaintiff will not have sustained either irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the brain, including the brain stem, at the time Defendants declare him dead and take subsequent actions under the Execution Protocol.

237. The Execution Protocol contains additional requirements relevant to Plan 1, allegations of which are incorporated here by reference. (See ECF No. 521-1, PageID 14160-78.)

2. Plan 2 of DRC Defendants' Execution Protocol

238. Plan 2 of DRC Defendants' Execution Protocol requires the peripheral intravenous injection, via five syringes, of five grams of thiopental sodium, 200 ml of a 25 mg/ml solution, followed by a saline solution flush. In practice, DRC Defendants fill the IV tubing with saline solution before injecting the execution drug, and they inject a saline solution flush following each syringe.

239. Five additional grams of thiopental sodium, 200 ml of a 25 mg/ml solution, are required to be obtained and kept available in the Equipment Room, to be drawn into five separate syringes and administered via peripheral IV injection if the primary five-gram dose of thiopental sodium "proves to be insufficient for the procedure."

240. Beyond the 10 grams prepared as described above, nothing in the Execution Protocol or DRC Defendants' informal execution policies ensures that additional quantities of thiopental sodium are kept available in the Equipment Room to be used in an execution. Upon information and belief, additional quantities of thiopental sodium beyond these 10 grams will not be present or available for DRC Defendants to use in an execution using Plan 2.

241. Defendants contemplate using thiopental sodium obtained under whatever name it may be available from Drug Source Defendants.

242. Defendants know or should know that Plan 2 causes death by suffocation, unless death occurs as a result of a painful heart attack.

243. Use of thiopental sodium in an execution carries a substantial risk of creating a paradoxical reaction, which occurs when a drug does not work as intended.

244. A paradoxical reaction to thiopental sodium would cause an individual to remain hyper-aware as the execution proceeds. As a result of that heighted state of

awareness, such an individual would experience severe pain and needless suffering from a heart attack or other pain associated with the process as the injected lethal drug does its work.

245. The risk of a paradoxical effect is even greater when the individual to whom the drug is being injected has suffered a brain injury, or has a history of aggression or impulsivity, a history of substance abuse, a history of psychiatric disorders, or characteristics that suggest PTSD.

246. Using thiopental sodium to kill in a lethal-injection execution creates a substantial likelihood the inmate will suffer a painful heart attack.

247. DRC Defendants know or should know that Plan 2 causes death by suffocation, unless death occurs by a painful heart attack.

248. Five injections of 1.0 grams of the thiopental sodium in a 25 mg/ml solution will not act directly to stop Plaintiff's heart.

249. Instead, five injections of 1.0 grams of the thiopental sodium in a 25 mg/ml solution will suppress Plaintiff's breathing, creating a lack of oxygen to his heart.

250. The lack of oxygen caused by five injections of 1.0 grams of the thiopental sodium in a 25 mg/ml solution will suppress the beating of Plaintiff's heart.

251. After five injections of 1.0 grams of thiopental sodium in a 25 mg/ml solution have been completed, Plan 2 of DRC Defendants' Execution Protocol calls for an Unnamed and Anonymous Execution Team Member ("Drug Administrator") to reenter the Execution Chamber to inspect the IV site for evidence of incontinence or infiltration and to listen to the prisoner for breathing and heart sounds. (DRC Policy 01-COMM-11, ECF No. 521-1, PageID 14174).

252. If the Drug Administrator does not hear any breathing or heart sounds, an "appropriate medical professional" (the County Coroner) shall evaluate the prisoner to confirm death.

253. Though Plan 2 of DRC Defendants' Execution Protocol does not define the phrase "evaluate the prisoner to confirm death," upon information and belief, by practice, the County Coroner listens to the prisoner for breathing and heart sounds.

254. Though Plan 2 of the Execution Protocol does not define the phrase "evaluate the prisoner to confirm death," upon information and belief, by practice, the County Coroner does not perform ECG or EEG examinations.

255. Though Plan 2 of the Execution Protocol does not define the phrase "sufficient time for death to have occurred," by practice, the Drug Administrator's evaluation and the County Coroner's evaluation both occur within approximately ten minutes following the five injections of 1.0 grams of thiopental sodium.

256. Within approximately ten minutes after five injections of 1.0 grams of thiopental sodium, Plaintiff's heart and breathing sounds will be undetectable.

257. Under Plan 2 of the Execution Protocol, after the County Coroner confirms death, Defendant Warden will declare Plaintiff dead by announcing a time of death. (DRC Policy 01-COMM-11, ECF No. 521-1, PageID 14175).

258. At the time Defendant Warden will declare Plaintiff dead by announcing a time of death, there is a substantial risk that Plaintiff will still have rhythmic electrical cardiac activity that can be detected through an ECG examination.

259. At the time Defendant Warden will declare Plaintiff dead by announcing a time of death, there is a substantial risk that Plaintiff will still have electrical activity in his brain that can be detected through an EEG examination.

260. Where the activity described in the preceding two paragraphs is present, Plaintiff is clinically and legally alive.

261. There is a substantial risk that Plaintiff's electrical cardiac activity and electrical brain activity will continue for as long as 45 minutes after breathing and heart sounds are undetected.

262. There is a substantial risk that Plaintiff will not have sustained either irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the brain, including the brain stem, at the time Defendants declare him dead and take subsequent actions under the Execution Protocol.

263. The Execution Protocol contains additional requirements relevant to Plan 2, allegations of which are incorporated here by reference. (See ECF No. 521-1, PageID 14160-78.)

C. Allegations regarding Drug Source Defendants' status as acting under color of law.

264. Plaintiff is informed and has reason to believe that Drug Source Defendants will act in concert with the DRC Defendants to carry out the mission-critical—but prohibited by law—task of procuring and supplying controlled substances to the DRC Defendants to carry out one or more executions.

265. Plaintiff is informed and has reason to believe that Drug Source Defendants are legally responsible, negligently or in some other actionable manner, for the events and occurrences described in this Third Amended Omnibus Complaint.

266. The Execution Protocol allows several different DRC Defendants or their agents to obtain execution drug(s) from a licensed pharmacist at the Ohio Department of Mental Health and Addiction Services, from a pharmacy, manufacturer, supplier or distributor, or from any other licensed pharmacist.

267. The Execution Protocol does not require that the DRC Defendants obtain the execution drugs from a pharmacy, manufacturer, supplier, distributor, pharmacist, or compounding pharmacy that is a legally operating business entity located within Ohio (or even within the United States) with all required federal and Ohio licenses and up-to-date regulatory inspections.

268. The Execution Protocol does not require that the DRC Defendants obtain the execution drugs from a pharmacist or compounding pharmacy licensed in Ohio (or even within the United States).

269. The Execution Protocol does not limit the source of execution drugs to an Ohio-licensed pharmacist working in the scope of his or her employment at an Ohio-licensed pharmacy or compounding pharmacy.

270. The DRC Defendants have now elected to involve, and, upon information and belief, are now recruiting or have already successfully recruited, one or more persons or entities—to wit, the Drug Source Defendants—who are appropriately described under the Execution Protocol as Support Staff because they have a specified role in the Execution Protocol—to provide the execution drugs.

271. Upon information and belief, the DRC Defendants have elected to obtain or to seek to obtain execution drug(s) from any number of the Drug Source Defendants.

272. Upon information and belief, Defendants plan to use or will use execution drug(s) for Plaintiff's execution that have been manufactured via compounding, or manufactured overseas and then imported into the United States, or supplied, distributed or otherwise provided to DRC Defendants by Drug Source Defendants.

273. Carrying out a state-sanctioned execution in Ohio has historically been a power reserved to the State. Likewise, procuring and providing to DRC drugs to use for a lethal-injection execution in Ohio has historically been a function performed exclusively by a State agency, to wit, the Ohio Department of Mental Health and Addiction Services (or its predecessor) and that agency's operations previously known as Central Pharmacy-Inpatient.

274. The Drug Source Defendants are willful, joint—and indeed, indispensable—participants in overt actions with the DRC Defendants necessary to carry out an execution in Ohio, with a substantial degree of cooperation between the Drug Source Defendants and the DRC Defendants, solemnized by contract, to create or otherwise provide to DRC Defendants execution drugs and use them in an execution in violation of numerous state, federal and constitutional provisions.

275. Recent amendments to the Ohio Revised Code confirm that Drug Source Defendants are considered by the State of Ohio to be "necessary" to the State's efforts to carrying out a lethal-injection execution, with virtually no difference in the eyes of the State of Ohio between DRC Defendants and Drug Source Defendants insofar as their respective necessity to carrying out an execution.

276. Ohio Revised Code § 2949.221, by intentionally blurring into nonexistence any distinction between Drug Source Defendants and DRC Defendants for purposes of

carrying out a lethal-injection execution, unambiguously establishes that Drug Source Defendants are state actors acting under color of law.

277. Section 7(C) of the legislative enactment that adopted § 2949.221 (i.e., HB 663, effective March 23, 2015) stated that the intent of the General Assembly in enacting § 2949.221 and related provisions of HB 663 is "to enable [DRC] to obtain the necessary assistance of persons in carrying out a court-ordered sentence of death by lethal injection or the drugs needed to administer such a sentence," by which was meant specifically the assistance of private persons and entities such as the Drug Source Defendants.

278. Upon information and belief, the Drug Source Defendants, by compounding, manufacturing, importing, or otherwise supplying execution drugs to the DRC Defendants to use in a state-administered execution, are performing and have assumed a function that was traditionally reserved to the State and performed by a public agency.

279. Because manufacturing, compounding, distributing, dispensing, introducing into interstate commerce, selling, delivering, holding or offering for sale, importing, and other actions related to pentobarbital or thiopental sodium to be used as execution drugs under Ohio's execution protocol are prohibited by numerous provisions of federal and state law, the Drug Source Defendants, by contracting or otherwise working with DRC Defendants, are jointly and willfully engaged with State officials in prohibited actions, and are thus acting under color of law.

280. Upon information and belief, Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 and others of the Drug Source Defendants

have contracted or otherwise agreed to work with DRC Defendants specifically for the purpose of providing specialized pharmaceutical services in the form of compounded drugs to be used for a lethal-injection execution, including for the planned execution of Plaintiff.

281. Upon information and belief, Drug Source Defendants have contracted or otherwise agreed to work with DRC Defendants specifically for the purpose of providing services in the form of procuring pentobarbital and/or thiopental sodium manufactured overseas and imported into the United States to be used for a lethal-injection execution, including for the planned execution of Plaintiff.

282. The Drug Source Defendants are or will be aware of the purpose and intent for which they will specifically manufacture, compound, supply, distribute or otherwise provide the execution drug(s) sought by the DRC Defendants, namely the execution of one or more readily identifiable condemned inmates scheduled for execution on a particular date at a particular time for a particular crime.

283. The Execution Protocol's delegation of a critical element of the execution process—manufacturing, compounding, importing, distributing or otherwise supplying the execution drug(s), to be used solely for executions on a known date and time and for a known inmate or inmates—to the Drug Source Defendants vests tremendous responsibility and authority in the Drug Source Defendants.

284. Upon information and belief, the DRC Defendants have never before vested such tremendous responsibility and authority in any such unknown private parties with respect to the execution process, and certainly not since Ohio began conducting executions by lethal injections in 1999.

D. Allegations related to using pentobarbital or thiopental sodium for an execution.

285. A "New Drug" under the federal Food, Drug & Cosmetic Act (21 U.S.C. § 321(p)) and Ohio Revised Code § 3715.01(9)(a), means a drug that is "not generally recognized . . . as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof."

286. Thiopental sodium and pentobarbital are Dangerous Drugs under Ohio law, for which Ohio law requires they may only be dispensed upon a prescription, Ohio Rev. Code § 4729.01(F)(1)(b), and for which Ohio law requires compliance with federal FDCA labeling and new drug approval requirements under 21 U.S.C. § 301, et seq. *See* Ohio Rev. Code §§ 3719.01(D), 3719(BB), 4729.01(F)(1)(a).

287. The FDA must approve any New Drug before the drug is introduced into interstate commerce, 21 U.S.C. § 355(a), and before any drug is sold, delivered for sale, held for sale, or given away, Ohio Rev. Code § 3715.65.

288. FDA approval of a New Drug must be for specific uses of a drug. To obtain FDA approval, drug manufacturers are required to demonstrate, through clinical trials, the safety and efficacy of a New Drug for each intended use or indication.

289. Any pentobarbital or thiopental sodium DRC Defendants might use for a lethal-injection execution of Plaintiff would have been introduced into interstate commerce, or sold, delivered for sale, held for sale, or given away.

290. Thiopental sodium has never been approved by FDA for any intended use, and is thus considered an unapproved New Drug such that all Defendants may not, regardless of the source, lawfully introduce thiopental sodium into interstate commerce, or sell, deliver for sale, hold for sale, or give away thiopental sodium.

291. No drug is, or ever has been, approved by the FDA as safe and effective for the purpose of causing a "quick and painless" death required by Ohio's execution statute.

292. Therefore, when used for the purpose of causing death in a human execution, Defendants' actions involving pentobarbital or thiopental sodium constitute using unapproved New Drugs under the FDCA and Ohio state law. *See* 21 U.S.C. §§ 321(p), 355; Ohio Rev. Code § 3715.65(A).

293. Before a New Drug can lawfully be administered to humans (other than through the doctor-patient relationship in the practice of medicine), an "investigational new drug application ('IND')" must be submitted by the entity administering the drug. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 697-98 (D.C. Cir. 2007).

294. To obtain approval of an IND Application, the applicant must engage in clinical investigation. Thus, to administer pentobarbital or thiopental sodium to inmates to cause their execution, DRC Defendants are required to submit an IND Application to the FDA and "shall not begin a clinical investigation . . . until the investigation is subject to an IND which is in effect." 21 C.F.R. § 312.20(a)-(b).

295. DRC Defendants flout these federal and state laws. DRC Defendants have never submitted any IND Application to the FDA for using pentobarbital or thiopental sodium in executions. Nor have DRC Defendants ever taken steps to submit an IND Application for using pentobarbital or thiopental sodium in an execution, and neither Ohio's execution statute nor the Execution Protocol includes such a requirement.

296. DRC Defendants have not submitted and do not intend to submit an IND Application for either pentobarbital or thiopental sodium to be used to attempt Plaintiff's lethal-injection execution.

297. Ohio's lethal-injection statute and the Execution Protocol, as written and as implemented, therefore purport to authorize DRC Defendants' use of unapproved New Drugs on a human in Plaintiff's attempted execution without satisfying the IND Application requirement established under the applicable federal and state regulations and statutes.

298. Federal and state laws prohibit introduction into commerce of any adulterated or misbranded product: "The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded" is a "Prohibited Act." 21 U.S.C. § 331; Ohio Rev. Code § 3715.52(A)(1).

299. Under federal law, a product is misbranded if it is "health-endangering when used [as] . . . prescribed." 21 U.S.C. § 352(j).

300. Under Ohio state law, a product is misbranded if it "is dangerous to health when used [as] . . . prescribed." Ohio Rev. Code § 3715.64.

301. Drug Source Defendants engage in a Prohibited Act under both state and Federal law by manufacturing, selling, delivering, holding or offering for sale pentobarbital or thiopental sodium to DRC Defendants to be used for a lethal-injection execution—and thus Drug Source Defendants are violating federal and state law by engaging in such actions—because those drugs are, by definition, misbranded by virtue of being "health-endangering" and "dangerous to health" because they will be used to execute Plaintiff.

302. Under federal law, a drug is adulterated if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. § 351(a)(2)(B).

303. A drug is also adulterated under federal law if "it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium." 21 U.S.C. § 351(b).

304. Under Ohio state law, a drug is adulterated if it "purports to be or is represented as a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and its strength differs from or its quality or purity falls below the standard set forth in those compendiums." Ohio Rev. Code § 3715.63(A)(5).

305. The DRC Defendants previously recognized the importance of not using adulterated controlled substances for execution drugs, when they agreed they would not use adulterated thiopental sodium for executions. *See* ¶¶ 641-642 below.

306. Drug Source Defendants engage in a Prohibited Act under federal law by manufacturing, selling, delivering, holding or offering for sale a drug product, namely pentobarbital or thiopental sodium for DRC Defendants to use in a lethal-injection execution of Plaintiff, that are not manufactured, processed, packed or held in a facility that is in conformity with current good manufacturing practices, and thus

Drug Source Defendants are violating federal and state law by engaging in such actions.

307. Drug Source Defendants engage in a Prohibited Act under both federal and Ohio state law by manufacturing, selling, delivering, holding for sale or offering for sale a drug product, namely pentobarbital or thiopental sodium for DRC Defendants to use in a lethal-injection execution of Plaintiff, that is not the same strength, quality and purity as that drug as identified in the USP and national formulary, and thus Drug Source Defendants are violating federal and state law by engaging in such actions.

308. The standard of practice of pharmacy in Ohio requires "(5) Performing drug regimen reviews with individuals by discussing all of the drugs that the individual is taking and explaining the interactions of the drugs; (6) Performing drug utilization reviews with licensed health professionals authorized to prescribe drugs when the pharmacist determines that an individual with a prescription has a drug regimen that warrants additional discussion with the prescriber." Ohio Rev. Code § 4729.01(B).

309. Prospective Drug Utilization Reviews are intended to maximize potential therapeutic benefit while minimizing potential harm to the patient through a review of the patient's drug therapy regimen including the current prescription in question.

310. The pharmacist is directed to ultimately use "professional judgment whether and in the patient's best interest to dispense the prescription." Ohio Admin. Code § 4729-5-20.

311. A pharmacist is required under Ohio law to perform the Prospective Drug Utilization Review. Ohio Admin. Code § 4729-5-21(B)(2) ("A pharmacist when dispensing a

prescription must . . . perform prospective drug utilization review pursuant to rule 4729-5-20 of the Administrative Code").

312. Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 violate these responsibilities under Ohio law to the patient's best interests when the drug product they dispense is for the purpose of killing Plaintiff, and thus Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 violate state law by engaging in such actions.

313. Ohio law also requires Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 to act "in a manner that is in the best interest of the patients served and to comply with all state and federal laws." Ohio Admin. Code § 4729-9-02(A)(2), (B).

314. Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 violate these state regulations by compounding, dispensing, distributing, or any other similar action the drugs for DRC Defendants to use to carry out a lethal-injection execution, because acting to facilitate the death of Plaintiff is not in his best interests, and because Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 violate several state and federal laws in the course of their actions related to execution drugs.

315. Controlled substances may not be dispensed without a valid prescription from a medical practitioner. 21 U.S.C. § 829(a)–(b).

316. Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100, like all pharmacists and pharmacies, may only dispense a prescription drug

product on the receipt of a valid drug order (Prescription) from a licensed practitioner authorized to prescribe.

317. The Ohio Medical Practice Act (Ohio Admin. Code § 4731-11-02), states that physicians cannot utilize a controlled substance for other than "legitimate therapeutic purposes," (§ 4731-11-02(F)), which would preclude their writing a prescription for execution drugs.

318. The restrictions under Ohio law on what may constitute a "valid" prescription are so critical they are reiterated in two separate provisions of Ohio's Administrative Code: the regulation governing "Manner of processing a prescription" (Ohio Admin. Code § 4729-5-21), and the regulation governing "Manner of issuance of a prescription" (Ohio Admin. Code § 4729-5-30).

319. Ohio law governing the "manner of processing a prescription" requires that a "prescription, **to be valid**, **must be** issued for a **legitimate medical purpose** by an individual **prescriber** acting in the **usual course** of his/her **professional practice**." Ohio Admin. Code § 4729-5-21(A) (emphases added).

320. The "responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. **An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription** and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law." *Id.* (emphasis added).

321. Ohio law governing the "manner of issuance of a prescription" similarly requires that a "prescription, **to be valid**, **must be** issued for a **legitimate medical purpose** by an

individual **prescriber** acting in the **usual course** of his/her **professional practice**." Ohio Admin. Code § 4729-5-30 (emphases added).

322. And "an order purporting to be a prescription issued not in the usual course of **bona fide treatment of a patient** is **not a prescription** and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law." *Id.* (emphases added)

323. Ohio law also requires that a prescription must "[b]e issued in compliance with all applicable federal and state laws, rules, and regulations." Ohio Admin. Code § 4729-5-30(18).

324. Accordingly, these Ohio prescription requirements echo those of requirements set forth under the federal Controlled Substances Act's explanation of the "purpose of issue of prescription": "A prescription for a controlled substance to be effective **must** be issued for a **legitimate medical purpose** by an individual **practitioner** acting in the **usual course** of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. **An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829)** and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 C.F.R. § 1306.04(a) (emphases added).

325. A pharmacist may not lawfully prepare and dispense a prescription drug product, such as controlled substances like pentobarbital or thiopental sodium, for anything other than a legitimate medical purpose.

326. The only valid prescription under federal and Ohio state law is one that is issued for a legitimate medical purpose, issued by an individual health-care practitioner with the requisite license to prescribe drugs, in the usual course of professional treatment or for legitimate or authorized research.

327. None of those DRC Defendants involved in procuring execution drugs or the Chief Justice of the Ohio Supreme Court is, under the law, an individual practitioner acting in the usual course who might be authorized to prescribe prescription drugs.

328. Execution is not a legitimate medical purpose.

329. Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are therefore violating federal and state law by preparing and dispensing a prescription drug product, namely pentobarbital or thiopental sodium, used to carry out a lethal-injection execution of unspecified condemned inmates.

330. General dispensing of controlled substances is also prohibited, because a valid prescription must be patient-specific. *See* 21 C.F.R. § 1306.04(b) ("A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.").

331. DRC Defendants rely solely on a resolution issued by the Ohio State Board of Pharmacy, R-2012-051, to claim that a certified copy of a Death Warrant issued by

the Ohio Supreme Court, ordering the execution of an inmate by lethal injection, has the same force and effect as a proper order for administration of the drug(s).

332. The State of Ohio delegated to the Ohio State Board of Pharmacy authority to " adopt rules in accordance with Chapter 119 of the Revised Code, not inconsistent with the law, as may be necessary to carry out the purposes of and to enforce the provisions of this chapter." Ohio Admin Code § 4729.26. In turn, Chapter 119 of the Administrative Code sets of Administrative Procedure. Resolution R-2012-051 was not a validly enacted rule under that chapter, and is therefore invalid as a matter of Ohio state law.

333. Additionally, Resolution R-2012-051, to the extent that it purports to authorize Defendants to obtain, provide, compound, administer, dispense, or distribute controlled substances without a prescription that satisfies the minimum requirements for a valid prescription under federal statutes and regulations or state statute, that Resolution is invalid as a matter of law because it is "inconsistent with the law."

334. The minimum requirements for what constitutes a valid prescription for prescription drugs established under federal law may not be overruled or disregarded by any provision in Ohio state law, regardless of whether any state statute or regulation was validly enacted under state law.

335. DRC Defendants do not obtain new execution drugs for each individual execution; instead DRC Defendants obtain a supply whenever they can, to be used for future executions.

336. This practice conflicts with the prohibition on "general dispensing" of controlled substances and thus DRC Defendants violate federal and state law by engaging in such actions.

337. Drug Source Defendants do not produce, provide, distribute or dispense execution drugs for each execution specific to the particular condemned inmate, but rather produce, provide, distribute or dispense a large supply that is not individualized to a particular condemned inmate. This practice conflicts with the prohibition on "general dispensing" of controlled substances and thus Drug Source Defendants violate federal and state law by engaging in such actions.

338. Defendants are violating federal and state law by preparing and dispensing pentobarbital or thiopental sodium other than to a single, identified individual when the pentobarbital or thiopental sodium is prepared and dispensed for DRC Defendants to use to carry out one or more lethal-injection executions.

339. The only FDA-approved form of pentobarbital is manufactured, sold and distributed as Nembutal.

340. At all times relevant hereto until December of 2011, the only FDA-approved source of Nembutal was the pharmaceutical company Lundbeck ("Lundbeck").

341. In July of 2011, Lundbeck instituted distribution controls to prevent the legitimate sale of Nembutal to departments of corrections in states that use lethal injection for capital punishment.

342. In December, 2011, Lundbeck sold its interests in Nembutal to Akorn Pharmaceuticals ("Akorn").

343. The only current FDA-approved source of Nembutal is Akorn. Akorn has retained Lundbeck's distribution controls.

344. All stocks of Nembutal sold prior to the institution of the Lundbeck/Akorn controls have expired.

345. Upon information and belief, Akorn has requested that supplies of the company's products that could be used for lethal injection be returned.

346. Defendants therefore have no legitimate or legal source of Nembutal.

347. Nembutal is available for purchase on the commercial market, however, regardless of whether it is available to DRC Defendants for executions.

348. Any pentobarbital to be used in executing Plaintiff will come from Drug Source Defendants via either: (a) the illegal importation of pentobarbital, a Schedule II controlled substance; or, (b) the illegal compounding of pentobarbital.

349. Federal and Ohio state drug control laws strictly govern possession, transportation, transfer, use, dispensing, and other such aspects related to controlled substances which are listed on "schedules" under federal statutes and regulations.

350. The Controlled Substances Act creates a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances.

351. Pentobarbital is a Schedule II-N controlled substance under the federal Controlled Substances Act, its implementing regulations and analogous or related federal and/or state laws such as the federal Food, Drug and Cosmetic Act. 21 C.F.R. § 1308.12.

352. By virtue of that fact, pentobarbital is a Controlled Substance under Ohio law. *See* Ohio Rev. Code §§ 3719.01(C), 3719.41, 3719.43 and 3719.44.

353. Thiopental sodium is a Schedule III controlled substance under the federal Controlled Substances Act, its implementing regulations and analogous or related federal laws such as the federal Food, Drug and Cosmetic Act. *See* 21 U.S.C. §§ 801-814; 21 C.F.R. § 1308.13(c)(3).

354. By virtue of that fact, sodium thiopental is a Controlled Substance under Ohio law. *See* Ohio Rev. Code §§ 3719.01(C), 3719.41, 3719.43 and 3719.44.

355. The Controlled Substances Act allows prescription of drugs only if they have a currently accepted medical use. 21 U.S.C. § 812(b).

356. The Controlled Substances Act also requires a "medical purpose" for dispensing the least controlled substances of those on the schedules. § 829(c).

357. The Controlled Substances Act, in its reporting provision, defines a "valid prescription" as one "issued for a legitimate medical purpose." § 830(b)(3)(A)(ii).

358. Under the Controlled Substances Act, physicians are considered to be acting as practitioners under the statute if they dispense controlled substances "in the course of professional practice." § 802(21).

359. The enforcement provision of the Controlled Substances Act states that "[e]xcept as authorized . . . it shall be unlawful for any person knowingly or intentionally . . . to . . . distribute or dispense . . . a controlled substance." 21 U.S.C. § 841(a).

360. Schedule II substances are generally available only pursuant to a written, nonrefillable prescription by a physician. *See* 21 U.S.C. § 829(a).

361. The Supreme Court of the United States has held that, under the Controlled Substances Act, dispensing controlled substances without a valid prescription is a federal crime. *See Gonzales v. Oregon*, 546 U.S. 243, 250-57 (2006).

362. Although it is generally a crime to dispense pentobarbital or thiopental sodium, an exemption is made for duly licensed and registered physicians and other entities that may lawfully prescribe controlled substances. 21 U.S.C. § 829.

363. The Attorney General of the United States has passed a regulation pursuant to the Controlled Substances Act requiring that every prescription for a controlled substance be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. *See* 21 CFR § 1306.04(a).

364. Defendants, or others acting on Defendants' behalf, do not obtain or dispense the lethal execution drugs pursuant to a valid prescription.

365. Upon information and belief, no duly licensed and registered physician or other entity prescribes the controlled substances DRC Defendants use to carry out a lethal-injection execution.

E. <u>Allegations related to compounded execution drugs.</u>

366. Modern day pharmacy practice relies almost entirely on pharmaceutical manufacturers to provide finished dosage forms (tablets, capsules, injectables, etc.) for the pharmacist's use.

367. American healthcare providers and patients have long relied on the regulation of pharmaceutical manufacturers by the FDA in order to set the standard for identity, purity, potency, and efficacy of prescription medications.

368. Manufacturers are heavily regulated to insure the quality of the dosage form and the safety and clinical effectiveness of the product.

369. Extensive (and expensive) testing is required before marketing as well as with each new batch produced, to insure quality, safety and effectiveness.

370. In very limited circumstances when a thoroughly tested commercial product will not fulfill a patient's needs, pharmacists are allowed to bypass the FDA quality requirements imposed on commercial manufacturers to extemporaneously prepare a personalized dosage form for a patient through the process called compounding.

371. Some of the DRC Defendants' previous execution protocols permitted only the use of "trade name" or "generic" drugs for a lethal-injection execution.

372. The DRC Defendants have eliminated those protective measures by including compounded pentobarbital or compounded thiopental sodium as drugs permitted under the protocol.

373. Compounded execution drugs provided to DRC Defendants by any of the Drug Source Defendants will **not** be manufactured, mixed, assembled, packaged, labeled, distributed, transferred, dispensed, or administered:

a) pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs, or

b) pursuant to a modification of a prescription made in accordance with a consult agreement, or

c) as an incident to research, teaching activities or chemical analysis, or

d) in anticipation of orders for drugs pursuant to valid prescriptions.

374. Traditional pharmacy compounding is a practice of the profession of pharmacy by which a licensed pharmacist, using Active Pharmaceutical Ingredients (APIs) and inactive ingredients obtained from FDA-approved facilities, combines, mixes, or alters ingredients in response to a prescription to create a medication tailored to the individual medical/therapeutic needs of an individual patient when that patient's individual needs cannot be met with an FDA-approved product.

375. On the other hand, non-traditional compounding pharmacy practice involved in the process of making lethal injection drugs resembles drug manufacturing more than it does practice of pharmacy. *See* Affidavit of Larry D. Sasich at 5, Exhibit 1. Non-traditional compounding involves the use of raw ingredients to manufacture a copy or substitute for an FDA-approved drug.

376. Even drugs made according to the enforceable sterile compounding standards issued by the United States Pharmacopeia (USP) Chapter 797 have a low standard of sterility assurance compared to the federal standard for manufactured, FDA-approved drugs. *See* Affidavit of Larry D. Sasich at 5, Exhibit 1.

377. The quality of raw bulk product, or Active Pharmaceutical Ingredients ("APIs"), used in compounding is suspect. *Id.* Because of high profit margins and low quality controls in the compounding industry, the market for API attracts counterfeiters. *See* Affidavit of Larry D. Sasich at 9, Exhibit 1. These counterfeit bulk drugs pose a health hazard because their manufacturer is often unknown, impurity profile is unknown, and the age, storage, and manufacturing environment likewise remain a mystery. *Id.*

378. Compounded drugs are not FDA-approved for any purpose. This means that the FDA does not verify the identity, purity, strength, potency, quality, safety, or effectiveness of compounded drugs. *See* Sarah Sellers & Wulf H. Utian, *Pharmacy Compounding*

Primer for Physicians: Prescriber Beware, 72 Drugs 2043, 20444-45 (2012)[3]; Sasich Aff. at 8, Exhibit 1.

379. This also means that compounded drugs lack any FDA finding of safety, efficacy, and manufacturing quality. *Id.* at 2048.

380. Chemicals that have not have been manufactured in a FDA-registered facility under current Good Manufacturing Practices have no assurance of consistent quality from lot to lot or from container to container.

381. DRC Defendants previously recognized the importance of not using compounded controlled substances for execution drugs, when they agreed they would not use compounded thiopental sodium for executions. *See* ¶¶ 641-642 below.

382. When it became inconvenient for DRC Defendants to obtain controlled substances for use in an execution, Defendants knowingly disregarded their previous agreement to not use adulterated or compounded execution drugs.

383. Defendants involved in producing compounded drugs are subject to federal and state drug laws identified in preceding paragraphs, including those regulating misbranded or adulterated drugs or the prescription requirements.

384. Defendants involved in producing compounded drugs are also subject to regulations, both federal and state, specific to compounding. These federal and Ohio state laws and regulations define two categories of compounding:

> (1) drugs compounded in a Pharmacy by a pharmacist, 21 U.S.C. § 353a and Ohio Admin. Code § 4729-16-03 (identified herein as a "503A Compounding Pharmacy"); or

[3] Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3695671/.

(2) sterile drugs compounded in an Outsourcing Facility, 21 U.S.C. § 353b and Ohio Admin. Code 4729-16-02 (identified herein as a "503B Outsourcing Facility").

385. The New Drug provisions of the FDCA are waived for activities within these two categories. Outside of these two avenues, however, a compounded drug product is an unauthorized New Drug, which may not be introduced or delivered into interstate commerce (21 U.S.C. § 355(a)), or sold, delivered for sale, held for sale, or given away (Ohio Rev. Code § 3715.65).

386. Manufacture, sale, or delivery, holding or offering for sale compounded drugs by Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 to be used by DRC Defendants for an execution is a Prohibited Act under federal and Ohio state law—and thus Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are violating federal and state law by engaging in such actions—because those compounded drugs, whether pentobarbital or thiopental sodium, would be misbranded and/or adulterated products.

387. Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100, regardless of whether acting as a 503A Compounding Pharmacy or a 503B Outsourcing Facility, are violating the federal and Ohio state law by compounding, dispensing, and distributing any execution drugs that are controlled substances.

388. Pharmacies may only dispense, not manufacture or distribute, controlled substances. 21 U.S.C. § 822(a)(2).

389. Dispensing a controlled substance such as pentobarbital or thiopental sodium is prohibited except in certain circumstances.

390. Under 21 U.S.C. § 802(10), "dispensing" a controlled substance "means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the

lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term 'dispenser' means a practitioner who so delivers a controlled substance to an ultimate user or research subject."

391. In an execution context, the inmate such as Plaintiff would be the "ultimate user," which means that, under the law, only Plaintiff himself would be able to legally take delivery of compounded pentobarbital or thiopental sodium from Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100.

392. Because Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 will dispense the compounded controlled substance(s) to be used for an execution to a person or entity other than Plaintiff, Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are violating federal and state law.

393. When pharmacies such as Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 provide controlled substances to anyone but the ultimate user (*i.e.*, the patient or a member of the patient's household), those pharmacies are distributing, not dispensing controlled substances.

394. Pharmacies such as Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are prohibited from distributing any controlled substances under the CSA unless the amount of controlled substances distributed is strictly limited (5% or less of all units dispensed or distributed) and other specific criteria are met. 21 C.F.R. § 1307.11(a). For example, the distribution must be "for

the purpose of general dispensing by the practitioner to patients." 21 C.F.R. § 1307.11.

395. Because Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are not distributing pentobarbital or thiopental sodium to a practitioner for general dispensing to patients, but rather distributing the drug to DRC personnel to be used to kill Plaintiff and other condemned inmates, Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are violating federal law by their actions.

396. Any distribution of compounded drugs to a prescriber is prohibited by Ohio law unless the drug is used "(a) [t]o treat an emergency situation; (b) [f]or an unanticipated procedure for which a time delay would negatively affect patient outcome; (c)[f]or diagnostic purposes." Ohio Admin. Code § 4729-9-25(A)(2).

397. Carrying out a lethal-injection execution is not an "emergency situation," nor is it "unanticipated" nor is the pentobarbital or thiopental sodium used in an execution context "for diagnostic purposes." Thus, none of those exceptions apply in the execution context, and Defendants are also violating this provision of Ohio state law by their actions.

398. If Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are operating as a 503A Compounding Pharmacy, they cannot compound, prepare, sell, dispense, or deliver drugs for DRC Defendants to use in an execution while remaining in compliance with all federal and state laws related to compounding.

399. If any of Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are acting as a 503A Compounding Pharmacy, they cannot legally compound or dispense a drug product compounded for an execution because of restrictions on how and when a 503A Compounding Pharmacy may compound and dispense drugs.

400. Similar to requirements for the dispensing of commercially available products, Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 cannot compound or dispense or sell a compounded product—including pentobarbital or thiopental sodium—unless it is pursuant to ". . . a **valid prescription order** or a notation, approved by the **prescribing practitioner**, on the prescription order that a compounded product is **necessary for the identified patient** . . . ." 21 U.S.C. § 353a(a).

401. Ohio law mandates compliance with federal § 353a. *See* Ohio Admin. Code § 4729-16-03(C).

402. Ohio law also mandates that a "prescription shall be compounded and dispensed only pursuant to a specific order for an individual patient issued by a prescriber." Ohio Admin. Code § 4729-16-03(J). *See also* Ohio State Board of Pharmacy, *Compounding In Ohio*, updated May 20, 2015, available at http://www.pharmacy.ohio.gov/Documents/TDDD/General/Compounding%20in%20Ohio.pdf.

403. There can be no valid prescription for compounded execution drugs, for the reasons explained in previous paragraphs.

404. Nor can there be any "notation . . . that a compounded product is necessary for the identified patient" because a drug product intended to kill the identified patient is not "necessary for the identified patient" as required by law.

405. Thus Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100, if acting as a 503A Compounding Pharmacist, will lack a legitimate prescription or notation from the prescribing practitioners of the necessity for a compounded drug, and thus Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are violating federal and state law by engaging in any preparation or provision of drugs to be used by DRC Defendants for a lethal injection execution.

406. Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are unable to satisfy the highly stringent requirements established in 21 U.S.C. § 353a(b), incorporated into Ohio law via Ohio Administrative Code § 4729-16-03(C), and thus Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are violating those provisions of federal and state law by preparing and providing compounded sterile injectable controlled substances for DRC Defendants to use in carrying out an execution.

407. If Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are operating as a 503B Outsourcing Facility, they cannot compound, prepare, sell, dispense, or deliver drugs for DRC Defendants to use in an execution while remaining in compliance with all federal and state laws related to compounding.

408. Compounding by a 503B Outsourcing Facility is subject to and regulated by the FDA's Current Good Manufacturing Practices (cGMP), the same set of requirements

for quality assurance that are imposed on other commercial pharmaceutical manufacturers.

409. Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are violating federal and state law by failing to comply with cGMPs, such as the requirement that any manufacturer conduct its own analytical testing and other testing (such as for the presence of pyrogens or other contaminants) throughout the manufacturing process before the drug is released to any other entity.

410. A 503B Outsourcing Facility is prohibited from producing drug products that are "essentially a copy of an approved drug." 21 U.S.C. § 353b(a)(5).

411. Under the law, a compounded drug is "essentially a copy of an approved drug" if, in relevant part, it is identical or nearly identical to a drug with an approved New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA). 21 U.S.C. § 353b(d)(2).

412. That restriction effectively prohibits a 503B Outsourcing Facility from producing and distributing copies of drugs which are FDA approved which may be used in an Ohio execution, *i.e.*, pentobarbital.

413. At this time, pentobarbital does not appear on the FDA's drug shortage list, and thus the provision in federal law that might permit copies of approved drugs in short supply does not apply here.

414. Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100, if acting as a 503B Outsourcing Facility, are violating federal and state law by producing any pentobarbital (for executions or for any other reason), because the

compounded drug product would be identical or nearly identical to an FDA-approved drug that is not on the FDA's drug shortage list at this time.

415. 503B Outsourcing Facilities are also not permitted to compounded products using bulk drug substances that do not appear on a list established by the Secretary of the Department of Health and Human Services identifying bulk drug substances for which there is a clinical need, or the drug compounded from that bulk substance appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing. 21 U.S.C. § 353b(a)(2)(A).

416. At this time, pentobarbital does not appear on the list identifying bulk drug substances for which there is a clinical need, nor does pentobarbital appear on the drug shortage list under 21 U.S.C. § 356e.

417. Thus, Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100, if acting as a 503B Outsourcing Facility, are violating federal and state law by compounding pentobarbital because using bulk drug (API) of pentobarbital is prohibited by this provision of the law.

418. Additionally, bulk drug substance may not be permissibly compounded by a 503B Outsourcing Facility if the bulk drug substance to be compounded is not accompanied by a valid certificate of analysis. 21 U.S.C. § 353b(a)(2)(D).

419. Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 cannot and/or will not produce a valid certificate of analysis for any drugs compounded for DRC Defendants to use in carrying out a lethal-injection execution, and thus Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are violating these provisions of federal and state law.

420. Unlike FDA-approved drugs manufactured by a reliable manufacturer and intended for therapeutic uses, drugs manufactured, compounded, imported, other otherwise provided by the Drug Source Defendants to DRC Defendants for injection into a condemned inmate such as Plaintiff are intended solely to kill that condemned inmate.

421. The Drug Source Defendants will know or will be able to readily ascertain the identity of the person or persons who are to be killed using the execution drugs they provide to DRC Defendants; they will know they are providing drugs that will be used to kill Plaintiff.

422. The Drug Source Defendants will know or will be able to readily ascertain the nature of the crime for which Plaintiff is to be executed.

423. There is no oversight, testing, checks, auditing or assessment for compliance with the law of the Drug Source Defendants themselves, their manufacturing or compounding facilities, their distribution, storage, packing, or anything else related to Drug Source Defendants' provision of drugs to be injected into a condemned inmate to carry out an execution.

424. Just as important, the Drug Source Defendants *will know* that there is no such oversight, testing, checks, auditing or assessment of their compliance with the law, in general and as related to provision of execution drugs to be used to kill Plaintiff, because they have been assured anonymity and immunity from certain professional repercussions under Ohio state law for a period of years from the point at which their assistance to DRC Defendants ceases.

425. Some Defendants—including at least one Drug Administrator—have admitted that they have thought of the inmate's victim and that victim's family while attempting to carry out an execution.

426. Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100, by each agreeing to violate his or her professional oaths, the relevant standards of care and federal and Ohio state law by manufacturing drugs exclusively to kill in a lethal-injection execution, necessarily lack the requisite ethical standards required of licensed pharmacists.

427. Pentobarbital and thiopental sodium for injections may be compounded only in a "sterile" compounding facility.

428. Sterile compounding pharmacies located within the State of Ohio are subject to certain federal and state regulations and relevant United States Pharmacopeia guidelines as adopted by the Ohio Board of Pharmacy by rule or policy. *See, e.g.*, Ohio Admin. Code § 4729-19-04.

429. Compounding pharmacies are not regularly or consistently inspected.

430. In fact, the Ohio Pharmacy Board does not track the number of compounding in-state pharmacies in Ohio, nor does Ohio require and/or provide training for inspectors to inspect compounding pharmacies.

431. Ohio does not track the number of inspections of compounding pharmacies in the state within a given year, nor does Ohio track the number of concerns about compounding pharmacies any such inspections reveal.

432. Ohio also does not track the number of disciplinary actions taken against in-state pharmacies for any reason over the last decade, nor does Ohio track the number of concerns with out-of-state compounding pharmacies that have been raised.

433. Errors that occur at compounding pharmacies may be caused by factors including: (a) use of substandard or contaminated APIs; (b) use of an incorrect formula to prepare a prescription drug; (c) maintenance of liquid dosages at inappropriately high temperatures, which may lead to chemical changes in the liquid; (d) failure to maintain a sterile facility and/or procedures; (e) failure to maintain manufacturing equipment in a sterile manner; (f) failure to properly store compounded products; (g) mislabeling medication; and (h) labeling medication with improper dispensing instructions for patient use.

434. When errors occur in compounding sterile preparations, including pentobarbital and thiopental sodium, harm can result from microbial contamination, excessive bacterial endotoxins, variability in intended strength and pH levels, unintended chemical and physical contaminants, and ingredients of inappropriate quality.

435. Bacteria and fungus are among the impurities commonly found in compounded injectable drugs, including pentobarbital and thiopental sodium.

436. Bacterial and/or fungal contamination will alter important attributes of the compounded pentobarbital or thiopental sodium used in Plaintiff's execution, including the final pH.

437. There is a substantial risk that alteration of the final pH of the compounded execution drugs used in Plaintiff's execution will create instability and/or incompatibility with human blood.

438. There is a substantial risk that, should the pH of the compounded execution drugs used in Plaintiff's execution be incorrect, Plaintiff will experience a burning sensation as it is being injected.

439. There is a substantial risk that, should the pH of the compounded execution drug(s) used in Plaintiff's executions be incorrect, it could form precipitates, or solid particles, of drug and other substances.

440. Contamination with particulate matter is also common in compounded injectable drugs.

441. Should solid, particulate matter of any kind be present in the compounded execution drug(s) used to execute Plaintiff, there is a substantial risk that Plaintiff will suffer unnecessary pain and suffering upon injection of the solution, including, but not limited to, the pain associated with a pulmonary embolism.

442. Bacterial and/or fungal contamination in compounded injectable solution produces endo-toxins and/or exo-toxins.

443. Endo-toxins and/or exo-toxins contained in compounded injectable solution can cause immediate and painful reactions associated with septic shock, including, but not limited to, a sudden rise in body temperature, a precipitous drop in blood pressure and seizure.

444. Should endo-toxins and/or exo-toxins be present in the compounded execution drug(s) used to execute Plaintiff, there is a substantial risk that Plaintiff will suffer unnecessary pain and suffering upon injection of the solution.

445. Bacteria and/or fungi commonly found in compounded injectable solution are growing organisms.

446. The presence of growing organisms accelerates chemical degradation.

447. Chemical degradation decreases the potency of injectable solutions such as pentobarbital and thiopental sodium.

448. Should bacterial and/or fungal contamination reduce the potency of the execution drug(s) used to execute Plaintiff, there is a substantial risk Plaintiff will not receive an adequate dose of the execution drug, thereby inflicting unnecessary pain.

449. The analytical testing provision in the Execution Protocol, stating that a sample of compounded execution drugs will be tested for potency and identity, will not resolve this problem.

450. That testing will be done (according to the Execution Protocol) approximately 30 days before execution, leaving plenty of time between the testing date and the execution date for continued growth of bacterial and/or fungal contamination and thereby continued reduction in potency of the drug between testing date and execution date.

451. The testing for potency and identity will not detect the presence of contaminants which would alert Defendants that, even though the potency standards might be sufficient 30 days in advance of the execution date, the compounded drug's potency will be reduced by the time the execution date arrives.

452. FDA inspections of some Ohio compounding pharmacies over recent years have resulted in warning letters identifying numerous deviations from relevant regulations and established Good Manufacturing Practices which resulted in the distribution of drugs that were adulterated, including deviations such as failure to monitor and

validate the manufacturing process, and a failure to reject product that was found to be incorrect in identity, strength, quality and/or purity.

453. The Execution Protocol does not ensure the receipt, storage, control and distribution of any compounded execution drugs only in the full and actual charge of an appropriately licensed health care professional.

454. The Execution Protocol, by its terms, allows receipt, storage, control and distribution of any compounded execution drug(s) by the Warden and the Drug Administrators, *i.e.*, persons other than an appropriately licensed health care professional, in violation of the relevant federal and State of Ohio laws.

455. The Execution Protocol contains no provision requiring the proper storage or verification of "beyond use" dates for any compounded execution drugs that might be used for an execution.

456. The Execution Protocol does not prohibit Defendants from using for an execution compounded drugs that are past their labeled "beyond use" dates.

457. The problems with the lack of FDA oversight of compounding came to national attention following the tragic event in 2012 when a compounding pharmacy providing medical facilities in 20 states with compounded steroid injections contaminated with fungal meningitis, which resulted in 64 patients dying, with a total of 751 patients falling ill after injection with the compounded drugs. *See* Centers for

Disease Control and Prevention, *Multistate Outbreak of Fungal Meningitis and Other Infections* (Oct. 23, 2013).[4]

458. As a result of the events of 2012, the FDA inspected some sterile compounding facilities and found serious quality-control problems, resulting in contaminated products. "Numerous recalls of sterile products have been conducted, and numerous pharmacies chose to stop sterile compounding after [the FDA] identified problems with their sterile compounded processes." *See* FDA, *Compounding—FDA Implementation of the Compounding Quality Act*.[5]

459. In addition, the five main testing facilities used by 90% of all the nation's large-scale compounding pharmacies in order to verify the strength, sterility, and purity of the compounding drugs were inspected by the FDA shortly after the October 2012 incident. *See* Kimberly Kindy, *Labs that test safety of custom-made drugs fall under scrutiny*, WashingtonPost.com, Oct. 5, 2013, *available at* 2013 WLNR 24973227.

460. Those labs were cited for more than 70 safety problems, including lack of sterile facilities and scientifically unsound testing. *Id.*

461. Various Ohio compounding entities have been found to have engaged in significant deviations from the applicable federal laws in ways that would constitute significant constitutional problems if done as part of the Execution Protocol.

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[4] Available at http://www.cdc.gov/hai/outbreaks/meningitis.html.

[5] Available at http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm375804.htm.

462. Without FDA approval of a drug and its manufacturing process, there is no reasonable assurance that the drug has the identity, purity, potency, and efficacy that it is represented to have. *See* Sellers & Utian, *Pharmacy Compounding Primer for Physicians: Prescriber Beware*, *supra*, at 2048.

463. With compounded drugs, there is a substantial risk that excipient (inactive) ingredients and APIs will be obtained from non-FDA-approved sources.

464. Compounding pharmacies are substantially likely to obtain the API for pentobarbital or thiopental sodium from companies in India or China or Pakistan, or other overseas companies that are not registered with or inspected by the FDA.

465. The API provided by these sources is highly suspect and there is no practical method to verify their quality, constitution, or uniformity in limited pharmacy settings such as retail compounding pharmacies.

466. The sources from which compounding pharmacies obtain the API's for their drug concoctions are often part of the global grey market, which is one of the leading sources for counterfeit drugs entering the United States.

467. In the unregulated market of APIs, a chemical labeled to represent a certain active ingredient may not actually contain the correct ingredient and it may contain harmful contaminants.

468. There is a substantial risk that Defendants will use pentobarbital or thiopental sodium manufactured by any of the Drug Source Defendants that compounded APIs obtained from non-FDA-registered facilities, *i.e.*, on the grey market.

469. There is a substantial risk that the APIs obtained on the grey market in order to compound pentobarbital or thiopental sodium for use in the execution protocol are impure, adulterated, sub-potent, and/or counterfeit.

470. There is a substantial risk that grey market APIs will come from plants in China, India, and/or other countries lacking the oversight and control necessary to produce uncontaminated, unadulterated, fully potent, and genuine APIs.

471. Plants in China providing APIs to the grey market have manufactured pesticides using the same equipment that is used to make APIs.

472. Several studies, including a survey conducted by the FDA in 2001, report a high prevalence of quality problems with various pharmacy-compounded drugs, including sub-potency and contamination.

473. A survey of compounded drug products was conducted by the FDA in 2006 to explore these issues further. The results showed that thirty-three percent of the compounded drugs failed analytical testing using rigorously defensible testing methodology.

474. A thirty-three percent quality failure rate of compounded drugs constitutes a substantial risk of harm.

475. Testing by the Missouri Board of Pharmacy, which is the only state that regularly tests compounded drugs, reveals that compounded drugs fail tests for potency and purity on average around twenty-five percent of the time.

476. A twenty-five percent quality failure rate of compounded drugs constitutes a substantial risk of harm.

477. Pentobarbital can be difficult to compound to the precise tolerances necessary to prevent an improper buffering (pH) level or to prevent the compounded drug from falling out of solution/precipitating.

478. Injecting a compounded solution that is buffered to the incorrect pH level will cause extremely painful burning upon coming into contact with human blood.

479. Injecting a drug that has precipitated or that will precipitate inside the recipient will cause the insides of the recipient's veins to feel burning, extremely painful sensations as if they are being scraped with sandpaper.

480. The chance of precipitation of compounded execution drugs is substantial at the least. For example, the solvent used in the typical formation of compounded pentobarbital is a water, propylene glycol, alcohol mixture (in a 50-40-10 ratio). The presence of the propylene glycol and alcohol suggest that pentobarbital sodium is not completely water soluble. This means if the compounded execution drug is mixed with additional water (thus diluting the alcohol and the propylene glycol), the pentobarbital will likely fall out of solution/precipitate, producing crystals of the drug floating in the container.

481. Because blood is essentially water, injecting the compounded pentobarbital rapidly, as DRC Drug Administrators do, will result in the drug precipitating in the vein, causing significant pain to the recipient.

482. Only a few other states have used compounded pentobarbital in executions, and their experiences demonstrate that the use of compounded execution drugs creates a very real and substantial risk that the inmate will suffer severe, unnecessary and inhumane pain and a lingering death.

483. Defendants are unable to reduce said substantial risk or have made it even greater because: (a) the manufacturer(s) of the APIs is/are unknown; (b) the impurity profiles of the APIs are unknown; (c) the age, storage, the manufacturing environment, or the manufacturing method of the APIs are unknown; (d) Defendants want to hide the identity of the compounding pharmacy and compounding pharmacist; and (d) Defendants want to hide the identity of any laboratory that conducts any analytical testing of the finished drug product under the Execution Protocol.

484. Within the grey market, secondary sources of APIs, *e.g.*, wholesalers and/or distributors, frequently use ambiguous and/or false statements in marketing APIs.

485. Statements from such secondary sources provide no reliable assessment of the purity, potency, identity, and/or lack of contamination of grey market APIs.

486. Intrinsic or extrinsic contaminants can be introduced during chemical manufacture or at any point during the chemical's synthesis.

487. Even if the API obtained and used by any Drug Source Defendants is not counterfeit and is domestically produced, there is a significant chance that it could be contaminated, adulterated, hyperpotent or hypopotent, the improper concentration, non-sterile, or myriad other characteristics creating a substantial likelihood that the drug(s) is not the execution drug(s) mandated by Core Element # 2, and a substantial likelihood that the lethal injection process could be extremely painful, or harm or handicap Plaintiff without actually killing him.

488. There is a substantial risk that Defendants will not identify the presence of harmful contaminants in compounded execution drugs that pose an immediate safety threat if administered intravenously.

489. Defendants, including, but not limited to, the Drug Source Defendants, do not have the ability to trace the APIs back to the original manufacturers for information on quality, packaging, storage, shipment conditions and chains of custody from a chemical's cradle to grave.

490. The Execution Protocol contains no provision by which Defendants will ensure that the raw API in any compounded execution drug is not imported, is sterile, is unadulterated, is not contaminated, or is otherwise anything other than pure raw API for pentobarbital or thiopental sodium.

491. Testing drugs after they have been compounded does not compensate for the absence of reliable, FDA-approved raw materials obtained from reputable, ethical, duly registered suppliers because post-compounding testing alone is not designed to ensure sterility or purity.

492. Any analytical testing results are invalid without any accompanying information about the testing protocols the testing facility employed, as well as information about the testing facility itself.

493. The United States Pharmacopeia and The National Formulary (USP-NF) General Chapter 797 provides the standards that pharmacies compounding sterile dosage forms of drugs (also referred to as compounded sterile preparations or CSPs), such as injectables like pentobarbital or thiopental sodium, are supposed to follow. See USP-NF Gen'l Ch. 797: Pharmaceutical Compounding—Sterile Preparations (June 2014).

494. Any compounded pentobarbital or thiopental sodium DRC Defendants would acquire from Drug Source Defendants would be derived from non-sterile API, and thus under

USP-NF General Chapter 797 would be high-risk-level CSPs. *See* USP-NF Gen'l Ch. 797: Pharmaceutical Compounding—Sterile Preparations (June 2014).

495. Although all pharmacies performing sterile compounding are supposed to follow USP-NF General Chapter 797, there is a lack of enforcement of these standards. The FDA defers enforcement of USP-NF General Chapter 797 to individual states. Jennifer Gudeman et al., *Potential Risks of Pharmacy Compounding*, Drugs in R&D vol. 13, iss. 1, at 3 (Mar. 23, 2013).

496. Only a handful of states have fully incorporated USP-NF General Chapter 797 into their regulations, and it is unclear whether any states have conducted, much less regularly conduct, inspections of any compounding pharmacies that sell CSPs to assure that they are in compliance with USP-NF General Chapter 797. *See id.*

497. The Ohio State Board of Pharmacy has incorporated USP-NF General Chapter 797 fully into its regulations, effective on January 1, 2015. See Ohio Admin. Code § 4729-9-21(C)(2) (eff. Jan. 1, 2015).

498. Accordingly, strict compliance with USP 797 is now required for an Ohio-licensed compounding pharmacy.

499. Defendants Pharmacies # 1-100 and Defendants Pharmacists # 1-100 violate the law when they fail to fully comply with USP 797.

500. If the pharmacy is a "non-resident" pharmacy—that is, it is a pharmacy located outside of Ohio—then the Ohio State Board of Pharmacy relies on the other state's board of pharmacy to inspect and enforce regulations. *See* Ohio Admin. Code § 4729-10-04. But again, other states might not require adherence to USP-NF General Chapter 797, much less regularly inspect pharmacies for compliance. *See*

Isaac Cohen, M.D., Isaac Cohen, MD, Rebuts—*Compounding Pharmacies: A Viable Option, or Merely a Liability*, Am. Academy of Phys. Med. & Rehab. 974, 980 (Nov. 2013).

501. Even if compounding pharmacies do actually follow USP-NF General Chapter 797 standards, those standards are less stringent, and produce less reliable drugs, than the FDA Good Manufacturing Practices. Jennifer Gudeman et al., *Potential Risks of Pharmacy Compounding*, *supra*, at 4 (comparing the failure rate of <2% for 3,000 FDA-approved commercial products tested from 1996 to 2001 to the failure rates ranging from 11% to 34% for compounded drugs randomly tested by the FDA, Missouri, and Texas).

502. Drugs compounded in accordance with USP-NF General Chapter 797 have a low standard of sterility assurance compared to the FDA standard. *Id.* ("USP <797> does not afford the same degree of sterility assurance for compounded drugs that GMPs provide for FDA-approved sterile products"). *See also* Affidavit of Larry D. Sasich at 5, Ex. ###.

503. There is a substantial risk of harm from Defendants' use of unverified ingredients, including the administration of an entirely incorrect chemical or active ingredient, administration of sub- or super-potent execution drugs, contamination with dangerous allergens or substances that may cause immediate anaphylactic reactions, and/or contamination with bacteria or fungus with immediate excruciating effects before Plaintiff is unaware, assuming it works even to that extent.

504. Even if the anesthetic drug is fully or partially effective, compounded drugs can cause serious harm and severe pain before loss of awareness.

505. Such harms include painful pulmonary embolisms resulting from deviations in potency or formation of precipitates within the body or from unanticipated drug incompatibilities; partial or complete lack of effect due to ingredient tampering; nausea and vomiting resulting from deviations in potency; suffocation and gasping for breath; immediate anaphylactic reactions or other excruciating effects resulting from contamination with dangerous allergens, bacteria, fungus, or other impurities; and serious burning pain on injection, as a result of incorrect pH and/or the drug precipitating inside Plaintiff's veins.

506. All of these circumstances would be expected to prolong the execution, make it a lingering death and a spectacle execution, and to multiply the pain and suffering beyond the objective of causing death.

507. Defendants' use of compounded—as opposed to manufactured, FDA-approved—drugs in executions creates a substantial, objectively intolerable risk that the drug will be the wrong identity or pH level, prone to falling out of solution/precipitating, ineffective, sub-potent, contaminated, unsterile, or otherwise adulterated.

508. There is a substantial, objectively intolerable risk that compounded execution drugs will be made using poor quality practices, and may be the incorrect identity, not buffered to the correct pH level, prone to falling out of solution/precipitating, ineffective, sub-potent, contaminated, unsterile, or otherwise adulterated.

509. Defendants' use of compounded drugs in executions makes it highly likely that Defendants will deviate from Core Elements of the Execution Protocol, and/or will apply the law disparately to similarly situated inmates, arbitrarily and recklessly.

510. Testing a sample of one solution made of a compounded drug, as Defendants' Execution Protocol calls for, is not reliable as to the identity, sterility, potency, or efficacy of the solution as a whole.

511. Similarly, testing one solution of several made of a compounded drug is not reliable as to the identity, sterility, potency, or efficacy of the other solutions made.

512. The risks associated with using execution drugs that are compounded in general are significantly enhanced by the risks associated with compounding performed by particular Drug Source Defendants.

513. Upon information and belief, Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are ill-equipped and lacking the expensive equipment necessary to compound sterile injectables.

514. Upon information and belief, Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are not possessing of the required high degree of skill, experience and training necessary to compound sterile injectables.

515. Upon information and belief, Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100, are ethically compromised and thus substantially likely to overlook contaminants or other of the myriad problems associated with compounded sterile controlled substances.

516. Upon information and belief, Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are aware of and take offense at Plaintiff's crime of conviction.

517. Upon information and belief, Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 know that what little oversight will be

employed regarding the compounded execution drugs they concoct will be limited to identity and potency.

518. Upon information and belief, Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 believe that Ohio state law provides blanket secrecy protection against any professional or legal ramifications for any harm done to Plaintiff by compounded execution drugs.

519. Thus, upon information and belief, there is a substantial risk that Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 will include unknown and/or undetectable substances or materials in the compounded drugs to cause Plaintiff great suffering and pain upon injection.

520. Accordingly, by DRC Defendants obtaining a particular batch of compounded execution drugs from Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 to be used for Plaintiff or others who immediately following on Defendants' execution schedule, there is a risk of harm that is even greater than the ordinary, substantial risk of harm from using compounded execution drugs in general.

521. As with any matter involving the exercise of judgment and professional skill, the viability of drugs manufactured via compounding is dependent upon the skill, expertise, and judgment of the compounder, i.e., the Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100.

522. And, in that sense, the Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are as essential to Defendants' administration of the Execution Protocol as the Execution Team members, the Medical Team, the Drug

Administrators, the Director, the SOCF Warden, the CCI Warden, or any other actors involved in any way in carrying out an execution.

523. Indeed, the professional contributions of the Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are just as important to the successful completion of an execution in a constitutional manner as that of any of the Execution Team members or other actors involved, including the Medical Team and Drug Administrators, the Director, and the Warden, if not more so.

524. Upon information and belief, Defendant Kasich has endeavored to shut down all state audits of private contractors until the end of his second term in office, see Janet Reitman, "Where the Tea Party Rules," Rolling Stone, Oct. 14, 2014,[6] thereby potentially ensuring that there will be no state audit of Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100.

525. Amendments to the Ohio Revised Code sought by Defendants and counsel for Defendants and signed into law by Defendant Kasich after an expedited process in a lame-duck legislative session, ORC § 2929.221-.222, attempt to keep secret the identity of any Drug Source Defendants, including Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100, thereby eliminating any meaningful, independent oversight of Defendants as it relates to execution matters, including matters related to the execution drugs.

[6] Available at http://www.rollingstone.com/politics/news/where-the-tea-party-rules-20141014.

526. The omission of any such oversight, redundancies, and other reviews and checks as to the Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 has created a blind spot in the execution process, one which enables any Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 who might be unscrupulous, corrupt, and/or incompetent to intentionally or unintentionally subvert the process, as a result of negligence but also as a result of malice.

527. There is thus a known, foreseeable and substantial, objectively intolerable risk, which Defendants have done nothing to eliminate or minimize, that compounded drugs used in the execution of Plaintiff will be defective in one or more of the following respects: (a) the compounded execution drugs are not what they purport to be and are not the drug(s) required by the written execution protocol; (b) the compounded execution drugs will not be the requisite potency and concentration for the intended usage, nor the potency and concentration required by the Execution Protocol; (c) the compounded execution drugs are contaminated (such as with impurities or other drugs), are adulterated such as with other substances that would make the execution painful, are not sterile to the same degree as manufactured by a reliable manufacturer making an FDA-approved product; (d) the compounded execution drugs are not fit for their intended usage; and/or (e) the compounded execution drugs have not been manufactured, compounded, produced, procured, conveyed, stored, handled, and dispensed in strict compliance with all applicable Ohio and federal statutes, regulations, or other laws or requirements.

528. Moreover, because they have omitted any oversight, redundancies, and other reviews and checks on the manufacturing facilities and/or work product of the Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100, the DRC Defendants will not determine in advance, if ever, whether a particular execution has been plagued or is about to be plagued by the negligence, incompetence, and/or malice of the Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100, including, for example, by the use of compounded execution drugs which include substances that intentionally or unintentionally cause the target of a particular execution to suffer something worse than the humane and dignified death to which he is entitled.

529. Because no one is exercising oversight or otherwise reviewing the manufacturing facilities and/or work product of the Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100, there is nothing to prevent such error or malfeasance from occurring and, what is just as bad, there is nothing to provide assurance to the intended target of the compounded execution drugs that such error or malfeasance cannot and will not occur in his execution.

530. Defendants knew or should have known each fact alleged herein and they have acted and/or continue to act, with deliberate indifference to the same.

F. Allegations related to imported execution drugs.

531. Imported thiopental sodium is, by definition, not ensured to be safe and effective because, as an unapproved drug, FDA have never found *any* thiopental sodium to be safe and effective.

532. Drugs to be used for an execution may not be exported to the United States from any European Union country.

533. Thus, any drugs to be used by DRC Defendants to carry out an execution are likely to originate in third-world countries or countries without rigorous drug-manufacturing oversight.

534. Upon information and belief, drugs to be used for an execution that are manufactured overseas and exported to the United States by Drug Source Defendants have not been manufactured in an FDA-registered and –inspected facility under quality assurance procedures designed to produce a safe and effective product, such as current Good Manufacturing Practices.

535. Upon information and belief, drugs to be used for an execution that are manufactured overseas and exported to the United States by Drug Source Defendants have not been shipped, handled, and stored under conditions that meet U.S. requirements to ensure the drugs' safety and effectiveness.

536. Upon information and belief, drugs—and their ingredients—to be used for an execution that are manufactured overseas and exported to the United States by Drug Source Defendants have not been evaluated for safety and effectiveness with the same level of oversight used for drug approval in the United States.

537. Upon information and belief, drugs to be used for an execution that have been manufactured overseas and exported to the United States by Drug Source Defendants do not contain all the required labeling information.

538. Upon information and belief, drugs to be used for an execution that have been manufactured overseas and exported to the United States by Drug Source Defendants

do not contain accurate, reliable labeling information, calling into question matters such as the true identity of a particular drug, and that drug's contents.

539. Upon information and belief, drugs to be used for an execution that are manufactured overseas and exported to the United States by Drug Source Defendants are not manufactured to the tolerances required by the USP (United States Pharmacopeia).

540. Upon information and belief, such drugs were manufactured to the lower tolerances contained in the IP (Indian Pharmacopeia), the EUP (European Union Pharmacopeia) or the BP (British Pharmacopeia).

541. Under the IP, EUP and BP monographs for formulation of thiopental sodium, the API must be a minimum of 84% thiopental content and 10.5% sodium content, which is mixed with 6% sodium carbonate.

542. Under the USP monograph, however, the API for thiopental sodium must be minimum 98% thiopental sodium (*i.e.*, not mixed with carbonate).

543. Analytical testing of any imported execution drugs is not required by Defendants' Execution Protocol.

544. Any discretionary analytical testing performed on imported execution drugs will be subject to the same fundamental problems and flaws identified above relating to analytical testing of Defendants' compounded execution drugs.

545. Defendants' use of imported drugs in executions creates a substantial, objectively intolerable risk that the drug will be the wrong identity or pH level, the incorrect concentration, ineffective, sub-potent, super-potent, contaminated, unsterile, or otherwise adulterated or misbranded.

546. There is a substantial, objectively intolerable risk that imported execution drugs will be made using poor quality practices, and may be the incorrect identity, the incorrect concentration, not buffered to the correct pH level, ineffective, sub-potent, super-potent, contaminated, unsterile, or otherwise adulterated or misbranded.

547. The use of imported drugs in executions makes it highly likely that Defendants will deviate from the Core Elements of the Execution Protocol and/or will apply the law disparately to similarly situated inmates, arbitrarily and recklessly.

548. Except for exceptions not applicable here, it is unlawful to import into the United States, and the FDA is required to refuse admission of, any misbranded or unapproved drugs. *Cook v. FDA*, 733 F.3d 1, 3 (D.C. Cir. 2013) (citing 21 U.S.C. § 381(a)).

549. A drug is "misbranded" under federal law if "it was 'manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered' with the FDA." *Cook*, 733 F.3d at 3 (quoting 21 U.S.C. § 352(o)).

550. Upon information and belief, any pentobarbital or thiopental sodium Drug Source Defendants intend to import or have imported to provide to DRC Defendants to use in a lethal-injection execution will not come from an FDA-registered facility, rendering such execution drug(s) "misbranded" and therefore unlawful to import into the United States. Imported thiopental sodium will also be misbranded under federal and state law for the reasons identified herein.

551. Thiopental sodium is an unapproved new drug that may not be lawfully introduced into interstate commerce under 21 U.S.C. § 355(a), because it is no longer "'generally recognized, among experts . . . as safe and effective' for its labeled use, [21 U.S.C.] §

321(p)(1)." *See Cook*, 733 F.3d at 3-4 (explaining that "[a]lthough thiopental has been used as an anesthetic since the 1930s, it is presently an unapproved new drug").

552. Likewise, thiopental sodium is an unapproved new drug because "it is undisputed that the FDA has *never* approved or even reviewed" thiopental (imported or manufactured domestically) "for safety and effectiveness" under 21 U.S.C. § 355(d). *Beaty v. FDA*, 853 F. Supp. 2d 30, 34-35 & n.2 (D.D.C. 2012), affirmed in relevant part sub. nom., *Cook*, 733 F.3d at 3-4.

553. Pentobarbital is an unapproved new drug as to its use for executions, because it has never been approved for use as an execution drug nor has it ever been the subject of an Investigational New Drug application (either filed or granted).

554. Under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 381(a), and the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(A), the FDA is required to refuse admission to thiopental sodium shipments coming into the United States. *See Cook*, 733 F.3d at 10-11.

555. Under *Cook* and the relevant provisions of federal law, importing thiopental sodium into the United States is prohibited, and thus Defendants may not legally import thiopental sodium to use for an execution.

556. Upon information and belief, however, Defendants have taken actions to try to import thiopental sodium, despite being on notice that such imports are illegal.

557. Those actions generated a letter to DRC Director Gary Mohr from Captain Domenic J. Veneziano, the Director of the Division of Import Operation, United States Public Health Service, which is part of the FDA.

558. In that letter, dated June 26, 2015, Captain Veneziano reiterated to Director Mohr that the permanent injunction entered in *Beaty* enjoins FDA "from permitting the entry of, or releasing any future shipments of, foreign manufactured sodium thiopental that appears to be misbranded or an unapproved new drug in violation of 21 U.S.C. § 355. Please note that there is no FDA approved application for sodium thiopental, and it is illegal to import an unapproved new drug into the United States." Letter from Domenic J. Veneziano, Dir., Div. of Import Operation, U.S. Public Health Serv., Food and Drug Admin., Dep't of Health and Human Serv., to Gary C. Mohr, Dir., Ohio Dep't of Rehab. and Corr. (June 26, 2015) (attached as Exhibit 2); *see also* Chris McDaniel, *Ohio Intended To Illegally Import Execution Drugs, FDA Letter Says*, BuzzFeed News (Aug. 18, 2015, 7:19 PM)[7]; Alan Johnson, *FDA warns Ohio not to illegally import execution drugs*, Columbus Dispatch, Aug. 19, 2015[8].

559. Federal law, *see, e.g.*, 21 U.S.C. §§ 952(a), 957, 958, also establishes that any attempt by Defendants to import pentobarbital to use for executions would be illegal, and DEA should seize such imports, because DRC Defendants do not possess the required DEA registration to legally import pentobarbital.

560. Federal law also establishes that if any person such as any Drug Source Defendant manufactures or distributes pentobarbital intending or knowing that the drugs will be

[7] Available at http://www.buzzfeed.com/chrismcdaniel/ohio-intended-to-illegally-import-execution-drugs-fda-letter#.iyEJXQjX2.

[8] Available at http://www.dispatch.com/content/stories/local/2015/08/19/FDA-letter-ohio-execution-drugs.html.

unlawfully imported into the United States, that person is also violating the Controlled Substances Act. 21 U.S.C. §§ 959, 960.

561. Federal law prohibits knowingly or intentionally furnishing false or fraudulent information in the documentation required to be permitted to import controlled substances. *See, e.g.*, 21 U.S.C. § 843(d); 19 U.S.C. §§ 1592, 542.

562. Upon information and belief, Defendants will not be permitted to import execution drugs unless Defendants or their agents provide false or fraudulent information regarding the attempted importation; there is no authorization for Defendants or their agents to import pentobarbital, and thiopental sodium may only be imported in limited situations that are not applicable to the execution context.

563. Thus, any import of pentobarbital by Defendants to use for executions would be necessarily based on fraudulent or false information.

564. Similarly, any importation of thiopental sodium by Defendants to use for executions would require providing false or fraudulent information to fraudulently invoke one of the limited exceptions for importing that drug.

565. Further, upon information and belief, Defendants or their agents provided false or fraudulent information in the course of applying for, and obtaining, a DEA Controlled Substance Registration for importing thiopental sodium by representing that procurement of execution drugs will be only in accordance with all applicable State and Federal Laws, licensing authorities, and ODRC policies and procedures.

566. Defendants have been on notice that predates DRC Defendants' application for the import registration that procuring the controlled substances to use for an execution under Ohio's Execution Protocols is impossible to do while remaining compliant with

all applicable Ohio and federal laws, licensing authorities, and/or ODRC policies and procedures.

G. Additional allegations regarding Ohio state law

567. It is a crime under Ohio state law for a person to knowingly obtain, possess, or use a controlled substance. Ohio Rev. Code § 2925.11(A). If one is a drug manufacturer, licensed health professional authorized to prescribe drugs, pharmacist, owner of pharmacies, or any other person who performs these actions in compliance with Ohio Revised Code Chapter 3719, 4715. 4723, 4729, 4730, 4731 and 4741, subsection (A) does not apply. Ohio Rev. Code § 2925.11(B)(1). If one is a person who obtained the controlled substance pursuant to a lawful prescription issued by a licensed health professional authorized to prescribe drugs, subsection (A) does not apply. Ohio Rev. Code § 2925.11(B)(4). Otherwise, however, whoever knowingly obtains, possesses, or uses a controlled substance is guilty of a felony of varying degree ranging from first to fifth depending on the amount of the drug involved. Ohio Rev. Code § 2925.11(C).

568. It is a crime under Ohio state law for any person to deceive another to procure the administration of, a prescription for, or the dispensing of, a dangerous drug. Ohio Rev. Code § 2925.22(A). Whoever commits such an Ohio crime is guilty of a felony of varying degree ranging from first to fifth. Ohio Rev. Code § 2925.22(B).

569. It is a crime under Ohio state law for a person by force, threat, or deception, administer to another or induce or cause another to use a controlled substance. Ohio Rev. Code § 2925.02(A)(1). It is also a crime under Ohio state law for a person to, by any means, administer or furnish to another or induce or cause another to use a

controlled substance, and thereby cause serious physical harm to the other person. Ohio Rev. Code § 2925.02(A)(3). If the person who administers a controlled substance to another or induces or causes another person to use a controlled substances is a drug manufacturer, wholesaler, licensed health professional, pharmacist, pharmacy or any other person who performs these actions in compliance with Ohio Revised Code Chapter 3719, 4729, 4730, 4731 or 4741, subsections (A)(1) and (A)(3) do not apply. *See* Ohio Rev. Code § 2925.02(B). Otherwise, however, whoever commits any of these actions is guilty of a felony of varying degree ranging from first to fifth degree. Ohio Rev. Code § 2925.02(C).

570. It is a crime under Ohio state law for a person to, by any means, administer or furnish to another or induce or cause another to use a controlled substance with purpose to cause serious physical harm to the other person. Ohio Rev. Code § 2925.02(A)(2). There is no exception to this criminal law, and whoever commits any of these actions is guilty of a felony of varying degree ranging from first to fifth degree. Ohio Rev. Code § 2925.02(C). If the controlled substance in question is a schedule II or schedule III drug, the crime is a second degree felony. Ohio Rev. Code § 2925.02(C)(1)(a), (C)(2)(b).

571. It is a crime under Ohio state law for any person, other than for lawful research, clinical, medical, dental or veterinary purposes, to obtain, possess or use a harmful intoxicant with the purpose to induce intoxication or similar physiological effects. Ohio Rev. Code § 2925.31(A). Whoever commits such an Ohio crime is guilty of a first-degree misdemeanor, unless the person has previously been convicted of a drug abuse offense, in which case violating § 2925.31(A) is a fifth-degree felony.

572. It is a crime under Ohio state law for any person to knowingly dispense or distribute a harmful intoxicant to a person age eighteen or older if the person who dispenses or distributes it knows or has reason to believe that the harmful intoxicant will be used in violation of section 2925.31 of the Revised Code. Ohio Rev. Code § 2925.32(A)(1). Whoever commits such an Ohio crime is guilty of a fifth-degree felony, or a fourth degree felony if the person has previously been convicted of a drug abuse offense. Ohio Rev. Code § 2925.32(D)(1).

573. It is a crime under Ohio state law for any person to sell, deliver, offer for sale, hold for sale, or give away any new drug unless an application with respect to the drug has become effective under 21 U.S.C. § 355. Ohio Rev. Code §§ 3715.65(A), 3715.99(D). Whoever commits such an Ohio crime is guilty of a fourth degree misdemeanor for the first offense, and guilty of a second degree misdemeanor for each subsequent offense. Ohio Rev. Code § 3715.99(D).

574. It is a crime under Ohio state law for any person to engage in Prohibited Acts as defined in Ohio Revised Code §§ 3715.52(A), 3715.99(D). Thus, it is a crime under Ohio state law to manufacture, sell, deliver, or hold or offer for sale any drug that is adulterated or misbranded, Ohio Rev. Code § 3715.52(A)(1), or to adulterate or misbrand any drug, Ohio Rev. Code § 3715.52(A)(2), or to receive in commerce any drug that is adulterated or misbranded and the delivery or proffered delivery of any adulterated or misbranded drug, for pay or otherwise, Ohio Rev. Code § 3715.52(A)(3). Whoever commits any of these Ohio crimes is guilty of a fourth degree misdemeanor for the first offense, and guilty of a second degree misdemeanor for each subsequent offense. Ohio Rev. Code § 3715.99(D).

575. It is a crime under Ohio state law for an Ohio law enforcement official to negligently fail to prevent or halt the commission of an Ohio crime; for an Ohio law enforcement, ministerial, or judicial officer to negligently fail to perform a lawful duty in a criminal case or proceeding; for a public official to recklessly fail to perform a duty expressly imposed by law with respect to the public servant's office; or a public official to do an act expressly forbidden by law with respect to the public servant's office. *See* Ohio Rev. Code § 2921.44(A)-(E). Whoever commits any of these actions is guilty of a misdemeanor of the second degree. *See* Ohio Rev. Code § 2921.44(F).

576. It is a crime under Ohio state law for any person to knowingly use or rely on an instrument that is not lawfully issued to assert jurisdiction over or determine the legal or equitable status, rights, duties, powers, or privileges of any person or property or to knowingly commit or facilitate the commission of a crime or for purposes of committing a felony. *See* Ohio Rev. Code §2921.52(B)(3)-(4). Whoever commits any of these actions is guilty of a felony in the third or fourth degree. *See* Ohio Rev. Code § 2951.52(D).

577. Pursuant to Ohio Revised Code § 2921.45, no public servant, under color of his office, employment, or authority, shall knowingly deprive, or conspire or attempt to deprive any person of a constitutional or statutory right. Whoever commits such actions is guilty of a misdemeanor of the first degree.

578. It is a crime under Ohio state law for any person employed by, or associated with, any enterprise to conduct or participate in, directly or indirectly, the affairs of an enterprise through a pattern of corrupt activity. Ohio Rev. Code § 2923.32(A)(1).

Whoever commits any of these actions is guilty of a felony in the second degree, or potentially the first degree. Ohio Rev. Code § 2923.32(B)(1).

579. It is a crime under Ohio state law for any person who has knowingly received any proceeds derived, directly or indirectly, from a pattern of corrupt activity to use or invest, directly or indirectly, any part of those proceeds, or any proceeds derived from the use or investment of any of those proceeds, in the acquisition of any title to, or any right, interest, or equity in, real property or in the establishment or operation of any enterprise. Ohio Rev. Code § 2923.32(A)(3). Whoever commits any of these actions is guilty of a felony in the second degree, or potentially the first degree. Ohio Rev. Code § 2923.32(B)(1).

H. Allegations related to the definitions of "Director" and "Warden" in the Execution Protocol

580. The Execution Protocol allows the DRC Defendants by its terms—and the Drug Supplier Defendants by implication—to deviate/vary from the written protocol if for any reason it is difficult, impractical or impossible to strictly follow the procedures in the written protocol.

581. The Execution Protocol also allows the DRC Defendants by its terms, and the Drug Supplier Defendants by implication, to deviate/vary from the written protocol if any situation arises that would make strictly following the written protocol difficult, impractical or impossible.

582. The Execution Protocol is silent on whether approval must be obtained *before* any variation from the protocol may occur.

583. The Execution Protocol requires that any variation of a "substantial nature" must be approved by the Director of DRC.

584. A previous written execution protocol, effective September 18, 2011, required that *only* the Director of DRC may authorize a variation from the mandates of the written protocol, and this Court previously rejected motions for injunctive relief on the basis that the evidence demonstrated that all deviations from the execution protocol would flow to one person, and one person only—only the Director of DRC—and only that single person could authorize deviations, thus ensuring strict compliance with, and the mandatory nature of, the written protocol's mandates.

585. Core Element # 5 of the Execution Protocol requires that "only the Director" of DRC can authorize a variation from the written execution protocol's mandates,

586. But since the DRC Defendants' adoption of the execution protocol effective April 28, 2014 ("the 2014 Execution Protocol"), and continuing through the present, the Execution Protocol has allowed an indeterminate set of persons with undetermined qualifications or experience to authorize deviations/variations from the written protocol, because it defines "the Director" as "the Director" *or anyone the Director designates*.

587. The Execution Protocol defines "Director," as follows: "As used in the policy the term 'Director' refers to the current Director of the Ohio Department of Rehabilitation and Correction *or the Director's designee*." (ECF No. 521, Execution Protocol, Section IV, p. 2 (PageID# 14161) (emphasis added).)

588. The term "Warden" is also redefined in the Execution Protocol to include not only the SOCF Warden or his Deputy Warden, but also "*the Director's designee*." (*Id.*, Section IV, p. 3 (emphasis added).)

589. Accordingly, by the terms of the Execution Protocol, deviations from the written protocol may flow to any of an undefined number of persons, rather than to a single person as required under the previous written protocol.

590. Furthermore, nothing in the Execution Protocol provides how "the Director's designees" will be identified, selected, designated, qualified, informed of such designation, or anything else; the protocol is silent other than to extend the Director's execution-matter authority to an unknown set of persons without restrictions.

591. Similarly, the Wardens at SOCF and CCI are delegated numerous critical tasks throughout the Execution Protocol, but "the Warden" does not mean just the Wardens at SOCF or CCI, but it also means *anyone the Director designates*.

592. Thus, during all times since the 2014 Execution Protocol, the Execution Protocol has exposed the illusory nature of the Core Elements on which the DRC Defendants have in the past defended their execution protocol against constitutional challenge, by redefining the terms "Director" and "Warden" to include anyone the Director (or the Warden) chooses to designate for a particular task or function, and without any minimal requirements on the qualifications, training, or competence of the "Director's designee" or the "Warden's designee."

593. This redefinition of key terms in such a material respect starting with the 2014 Execution Protocol has effectively caused a substantial diminution if not outright elimination of Core Element # 5 in the Execution Protocol, even while the DRC Defendants seek to maintain the pretense that all core protections still exist in the Execution Protocol.

594. It used to be that the term "Director," as used in the written execution protocol, meant just that, i.e., the Defendant Director of DRC, in this case Defendant Gary Mohr. It likewise used to be that the term "Warden," as used in the written execution protocol, meant just that, i.e., the Defendant Warden of SOCF, in this case Defendant Donald Morgan.

595. Thus, when written execution protocols that preceded the 2014 Execution Protocol included as key provisions that the "Director" or the Warden" would be responsible for a certain task or function as set forth in the written execution protocol, including the Core Elements, there was no ambiguity as to who was responsible or where the accountability lay. The buck stopped with the Director, and that meant the Director himself.

596. Only the person of the Director himself was allowed to authorize a variation from the procedures stated in the written execution policy, although allegedly not even the Director could authorize a deviation or variation from any of the four Core Elements enumerated in such written execution protocols that preceded the 2014 Execution Protocol.

597. But those protections and assurances were eliminated as a result of the DRC Defendants' definitional changes starting with the 2014 Execution Protocol and continuing in the Execution Protocol. The Execution Protocol now unambiguously allows the "Director" and the "Warden," as those terms are everywhere used in the Execution Protocol, to be one and the same person, "the Director's designee," and that person might be neither the actual Director nor the actual Warden. Or alternatively, these changes mean any of a wide variety of persons could function as

"the Director" or "the Warden" at any given moment and at any given point during Defendants' administration of the Execution Protocol to a given inmate. "The Director" for purposes of authorizing one particular deviation from the written protocol might be different than "the Director" for purposes of authorizing a different deviation minutes, hours, days, or weeks later.

598. Nowhere does the Execution Protocol impose any restrictions whatsoever on the delegation of functions to the "Director's designee." The delegation is not regulated or constrained in any way at all in the Execution Protocol.

599. Nothing in the Execution Protocol provides how the Director's designee will be identified, selected, designated, qualified, informed of such designation, or anything else; the protocol is silent other than to extend the Director's execution-matter authority to an unknown set of persons without restrictions of any kind.

600. The policy allows for any and all of the "Director's" and/or "Warden's" duties and responsibilities in the execution process, whether specified in the Execution Protocol or not, to be delegated to some unidentified designee or designees at any time, in any context, and for any reason. Delegation may thus occur in some executions, but not others; it may pertain to only some functions or it may pertain to every single function; all as the Defendant Director, or any successor Director, may in the exercise of unbridled discretion choose to allow for a particular execution.

601. Not only are there no restrictions on the functions that can be delegated, but there are no restrictions or requirements on the competence, training, judgment, skill, or qualifications of who may be tabbed to be the "Director's designee." No minimal requirements have been established. There is no assurance that a "designee" has any

knowledge of the execution process, much less that he/she is willing and/or able to enforce compliance with, and will not vary from, the Core Elements of the written execution protocol. There is, in short, no accountability required by the Execution Protocol.

602. A particular plaintiff being executed will have no clue as to which pattern of delegation, if any, will be used in *his* execution, because that is all a matter left to the arbitrary discretion of the Director or his designee. And, as such, by this newly adopted allowance of unbridled and unrestrained delegation, the DRC Defendants have further guaranteed that similarly situated plaintiffs will not be treated the same, as some will have untrained, unaccountable, and/or unknown "Director's designees" making the key decisions in their execution, despite the facial assurances of the Execution Protocol, whereas others will have the Director himself.

603. The hierarchical oversight structure which the DRC Defendants previously presented to this Court, which terminated at the top in a single individual to whom all responsibility, communications, and potential deviations from the written protocol ultimately flowed up, and from whom every single authorization required by the Core Elements flowed down, is now merely illusory, making all elements of the Execution Protocol more akin to guidelines than mandatory requirements from which deviation will not be allowed absent authorization by a single person.

604. The use of untrained, unaccountable, and/or unknown "designees" in the execution process, and to perform the important duties of the Director and/or Warden, is itself a violation of one or more Core Elements of the Execution Protocol because, among other reasons, there is no assurance that such designees are willing and/or able to

enforce the performance of an execution in a professional, humane, sensitive, and dignified manner and in accordance with, and without variance from, the Core Elements, and there is also no assurance that such designees will do so with the judgment, skill, and experience required for such a solemn task.

605. And, even if not itself a violation of Core Elements of the Execution Protocol, the use of untrained, unaccountable, and/or unknown "designees" in the execution process, and to perform the important duties of the Director and/or Warden, is so offensive to the spirit, purpose, and intent of the Core Elements of the Execution Protocol that such use must be deemed a violation of such Core Elements.

606. At bottom, the execution policy and Execution Protocol now make equal treatment of similarly situated individuals dependent upon the subjective interpretation and application of the Execution Protocol by any undefined person at any time and at any point in administration of the Execution Protocol, for any reason.

607. Similarly, equal treatment of similarly situated individuals is dependent upon the subjective interpretation and application of the Execution Protocol by any particular Director of DRC, which can and will change from Director to Director, and from "Director's designee" to "Director's designee," without restrictions, all from execution to execution.

608. To the extent the Defendant Mohr has previously expressed his intention that he would only delegate Defendant Voorhies to act as the Director's designee for any purposes under the Execution Protocol, that intention has not been included or otherwise memorialized in the Execution Protocol.

609. Additionally, the stated intentions of one Director, on such an important issue, are not sufficient to alleviate the deficiencies in the Execution Protocol, as identified in the preceding paragraphs, concerning the discretion conferred under the Execution Protocol for the Director to delegate all relevant duties and responsibilities to a Director's designee; DRC Defendants abide by previously stated sworn testimony until they decide not to.

I. Additional allegations related to the contents of Defendants' Execution Protocol.

610. Beginning with the 2013 Execution Protocol, the DRC Defendants made discretionary many of the formerly hard deadlines required by the protocol, thus lessening, rather than strengthening, the procedural protections afforded to a condemned inmate.

611. The 2015 Execution Protocol maintained those discretionary deadlines.

612. The 2013 Execution Protocol allowed "the Medical Team" the unfettered, unguided discretion to determine, at any time, which execution method will be used for any given inmate, by granting "the Medical Team" the unfettered, unguided discretion to determine, at any time, whether "available" execution drugs are "unusable."

613. The 2015 Execution Protocol maintained that discretionary language.

614. The Execution Protocol does not contain any substantive or procedural provisions by which execution drugs will be deemed "available," or "useable."

615. The Execution Protocol contains no substantive or procedural provisions by which "the Medical Team" will reach its decisions, such as how many Medical Team members must make the decision, whether the decision must be unanimous or

something else, whether any such decision may be unilateral by a single member of the Medical Team, or anything else.

616. The Execution Protocol does not actually require that Defendants notify the condemned inmate of how he or she will be executed, since that determination can be made "at any time" by some unknown number of the Medical Team using an unknown, undefined decisional process.

617. Defendants fail to conduct the evaluations required under the Execution Protocol sufficiently to ensure against the substantial risk of harm created by the intravenous administration of a Plan 1 or Plan 2 execution.

618. DRC Defendants previously testified under oath and assured this Court that they would not use compounded execution drugs, including thiopental sodium.

619. DRC Defendants have testified under oath and assured this Court that they would not use imported execution drugs.

620. DRC Defendants have previously testified under oath and assured this Court that they would not use expired execution drugs, and that they would not use expired execution drugs that have been given an extended expiration date.

621. Using imported execution drugs creates a substantial risk of serious harm to Plaintiff, because there is a substantial risk that such drugs are contaminated, adulterated, not of the correct identity, super- or sub-potent, or in myriad other ways not identical in make and quality to domestically produced execution drugs, because imported execution drugs have not been subject to the same stringent quality and manufacturing standards to which domestically produced drugs are subjected. Accordingly, there is a substantial risk of harm to Plaintiff, including serious physical

and/or mental or psychological pain and suffering, a lingering death, a spectacle execution that is not dignified, and other risks that are objectively intolerable but which Defendants ignore.

622. Using expired execution drugs or drugs that are past their use-by date or which have been given an extended expiration date creates a substantial risk of serious harm to Plaintiff, because there is a substantial risk that such drugs are contaminated, adulterated, not of the correct identity, super- or sub-potent, or in myriad other ways not identical to non-expired execution drugs. And that, in turn, creates a substantial risk of serious harm to Plaintiff, including serious physical and/or mental or psychological pain and suffering, a lingering death, a spectacle execution that is not dignified, and other risks that are objectively intolerable but which Defendants ignore.

623. Using compounded execution drugs creates a substantial risk of serious harm to Plaintiff, as identified in other paragraphs of this Third Amended Omnibus Complaint.

624. When the DRC Defendants modified 01-COM-11, effective October 10, 2013, they did not include any explicit prohibition on using drugs that are imported or past their use-by date or expiration date, despite recommendations that such changes be made in the formal policy revision.

625. All subsequent execution protocols, including the 2015 Execution Protocol, also do not include any explicit prohibition on using drugs that are imported or past their use-by date or expiration date.

626. Despite previous sworn testimony and assurances to this Court, Defendants now disclaim any prohibition on using imported execution drugs to carry out an execution

pursuant to the Execution Protocol, and have in fact taken concrete steps to try to obtain imported execution drugs.

627. Despite previous sworn testimony and assurances to this Court, Defendants now disclaim any prohibition on using compounded execution drugs to carry out an execution pursuant to the Execution Protocol, and have in fact changed the written protocol to explicitly allow their use of compounded execution drugs.

628. Defendants recently represented to this Court that they have not, and will not, illegally obtain execution drugs, but Defendants' purported adherence to that informal policy is undermined by, for example, evidence that Defendants took concrete steps to obtain imported execution drugs that Defendants knew or should have known are illegal to import.

629. Thus, Defendants have demonstrated that they will alter their positions as related to execution drugs as Defendants deem necessary to carry out an execution.

630. In light of Defendants' history of changing their positions on execution drugs that may be used for an execution, along with their previous refusal or failure to destroy or otherwise divest themselves of the expired execution drugs in their possession, and their simultaneous insistence that they will not and have not illegally obtained execution drugs when the available evidence suggests intentions otherwise, there is a substantial risk that Defendants, finding it difficult or impossible to carry out an execution using only non-imported, legally obtained and legally dispensed, distributed and administered execution drugs that are not expired and not past their use-by date, will resort to using drugs that are illegally obtained, dispensed,

distributed or administered or expired or past their use-by date, despite previous sworn testimony and assurances to this Court.

631. The changes to Defendants' execution protocol from the time that lethal-injection was first adopted as an execution method in Ohio increase the risks of harm associated with the protocol and Defendants' application of the execution protocol to Plaintiff.

632. Recent revisions to the Ohio Revised Code, § 2949.221-222, that were specifically sought by Defendants and signed into law by Defendant Kasich significantly reduce, if not entirely eliminate, the procedural protections the Execution Protocol allegedly provides, by attempting to hide from disclosure (and thus any meaningful oversight) a wide variety of factual information related to Defendants and the administration of the Execution Protocol.

633. When information was previously uncovered about DRC Defendants and their actions related to executions, troubling constitutional violations were revealed. Defendants claim to strictly adhere to the Execution Protocol and to follow the law in carrying out executions, but only through meaningful independent oversight can that claim be assessed. By drawing a cloak of secrecy over virtually everything related to executions, Defendants substantially increase the significant and demonstrated risk of unconstitutional and illegal activity in which Defendants engage related to executions.

J. Defendants' informal execution policies

634. The Execution Protocol, by its own terms, must be applied "in accordance with all applicable policies, administrative regulations, and statutes." 2105 Execution Protocol, Sec. III at pp. 1 (ECF No. 521-1, Page ID# 14160).

635. Upon information and belief, Defendants will employ an overarching execution policy that encompasses their informal execution policies, as well as the written execution protocol designated DRC Policy 01-COM-11 that is operable at the time, to execute Plaintiff.

636. Defendants' overarching execution policy includes admissions and representations the DRC Defendants or their predecessors have made in response to discovery requests propounded during the course of the instant litigation.

637. Defendants' overarching execution policy also includes representations that the DRC Defendants have made in various pleadings, motions and proceedings throughout the course of the instant litigation, including testimony presented in hearings before the Court.

638. When there is substantial overlap and correlation between a Core Element and federal and Ohio state statutes and regulations, those federal and Ohio state statutes and regulations are implicitly incorporated into the Execution Protocol such that violation of the federal or state law constitutes a deviation from the relevant Core Element. *In re: Ohio Execution Protocol Litig. (Phillips)*, No. 2:11-cv-1016, 2013 WL 5963150, 2013 U.S. Dist. LEXIS 159680, *82-84 (S.D. Ohio Nov. 7, 2013).

639. When Defendants have made concessions or representations that amount to unwritten or informal policies or practices incorporated into the Execution Protocol, then violation of those unwritten or informal policies or practices constitutes deviation from the relevant portion of the Execution Protocol.

640. One or more of the DRC Defendants have testified under oath that the written execution protocol is actually considered more akin to discretionary "guidelines"

rather than binding, mandatory law, and that the execution policy and written execution protocol gives Defendants discretion to deviate/vary from the policy and protocol's mandates to carry out an execution. The changes to the written protocol in the 2013 Execution Protocol, continued forward in all subsequent execution protocols including the 2015 Execution Protocol, again reflect this discretionary approach, rather than reject it.

641. On or about August 17, 2010, including in a sworn affidavit signed by the Director of DRC on or about August 20, 2010, the DRC Defendants made several commitments which they represented are part of their "informal" execution policy. (*See Cooey*, ECF No. 817; *see also Cooey*, ECF No. 817-1, PageID 17564-65.) Several of these commitments were sworn and filed on the record of this case.

642. Among Defendants' informal execution policies are the following:

- Defendants will not commence any execution unless they have, on hand in the Death House at SOCF, at least 10 grams—*i.e.*, a full 5-gram dose and a full 5-gram back-up dose—of the lethal execution drug.
- If Defendants do not have 10 grams of the Plan 1 or Plan 2 drug on hand in the Death House, Defendants will not commence an execution.
- Defendants will not transfer an inmate scheduled for execution to SOCF unless Defendants have 10 grams of the intravenously injected execution drug at SOCF.
- Defendants will not use imported execution drugs.
- Defendants will not use any execution drug that is expired at the time of the scheduled execution, according to the expiration date stamped on the original manufacturer's packaging.
- Defendants will use only execution drugs that are pure, unadulterated, unexpired, not compounded, and in the sealed, original manufacturer's packaging.

643. These informal policies contemplated thiopental sodium as the drug to be administered via IV injection, which Defendants used in the execution of Frank Spisak on February 17, 2011.

644. The 2015 Execution Protocol includes pentobarbital as the lethal drug under Plan 1, and thiopental sodium under Plan 2.

645. Defendants' policies that explicitly apply to thiopental sodium remain binding as to Defendants' inclusion of thiopental sodium in the 2015 Execution Protocol.

646. Further, the concerns that underpinned Defendants' informal policies as to thiopental sodium apply with equal weight to the use of pentobarbital, or any other execution drug(s) Defendants may contemplate.

647. The Director of DRC has testified under oath that Defendants would not use expired or imported execution drugs for an execution, and this Court has held that Defendants are bound by that testimony.

648. There is substantial overlap and correlation between Core Element # 2, which establishes that "the drugs required by this policy shall be used," and the federal and Ohio state statutes and regulations related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, prescribing requirements, and the practice of pharmacy, as those federal and state statutes and regulations tightly regulate, and/or control access to, the very drugs Defendants intend to use in the Execution Protocol, such that those federal and state administrative regulations and statutes are implicitly incorporated into Core Element # 2.

649. There is substantial overlap and correlation between Core Element # 1 which establishes that "three Medical Team Members, two of whom are authorized to administer drugs under Ohio law, shall be used in the conduct of court-ordered executions," and the federal and Ohio state statutes and regulations related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, prescribing requirements, and the practice of pharmacy, as those federal and state statutes and regulations tightly regulate, and/or control access to, and the authorization to administer, the very drugs Defendants intend to use in the Execution Protocol, such that those federal and state administrative regulations and statutes are implicitly incorporated into Core Element # 1.

650. There is substantial overlap and correlation between Core Element # 3, which establishes that "[f]unctions required to be performed by medically-qualified persons, as described in this policy, shall be performed by Medical Team Members," and the federal and Ohio state statutes and regulations related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, prescribing requirements, and the practice of pharmacy, medicine and/or nursing, as those federal and state statutes and regulations tightly regulate, and/or control access to, the very drugs Defendants intend to use in the Execution Protocol, and thus who can be considered "medically qualified" under those laws and as to which functions, such that those federal and state administrative regulations and statutes are implicitly incorporated into Core Element # 3.

651. On or about September 18, 2015, Defendants represented to the Court that Defendants have not, and will not, illegally obtain execution drugs, thereby implicitly incorporating into the Execution Protocol, by concession or representation that amounts to an unwritten or informal policy or practice, all federal and state administrative regulations and statutes related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, prescribing requirements, and the practice of pharmacy, medicine, and/or nursing, as those federal and state statutes and regulations tightly regulate, and/or control access to, the very drugs Defendants intend to use in the Execution Protocol.

652. On or about September 18, 2015, Defendants represented to the Court that Defendants have not, and will not, illegally obtain execution drugs, thereby implicitly incorporating into the Execution Protocol, by concession or representation that amounts to an unwritten or informal policy or practice, all federal and state administrative regulations and statutes that are overlapping with the Execution Protocol by virtue of regulating or otherwise controlling matters related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, prescribing requirements, and the practice of pharmacy, medicine, and/or nursing, as those federal and state statutes and regulations tightly regulate, and/or control access to, the very drugs Defendants intend to use in the Execution Protocol.

653. Also among Defendants' informal execution policies are the following provisions concerning Defendants' possession of a sufficient quantity of the intravenously

injected execution drug. Notably, these provisions are related, but they are discrete provisions with different requirements:

- A "notice" provision stating that DRC Defendants "will provide notice to a condemned inmate's counsel and Plaintiffs' counsel (if different) within a reasonable time period (no less than 5 days) before an execution if [DRC] does not have in its possession at least 10 grams of thiopental sodium at that time," (*Cooey*, ECF No. 817-1, PageID 17564-65); and
- A "reprieve" provision stating that "[c]oncurrent with such notice to counsel, [DRC Defendants] will also immediately seek a reprieve from the Governor related to that condemned inmate's execution," (*id.* at PageID 17565).

654. Also among Defendants' informal execution policies are the following provisions related to any intent or action by DRC Defendants to change their written execution protocol. Notably, these provisions are related, but they are discrete provisions with different requirements:

- A "notice" provision stating that DRC Defendants "will provide notice to the Court, to a condemned inmate's counsel and to Plaintiffs' counsel (if different) within a reasonable time period (no less than 30 days) before an execution if [DRC] intends to change the written execution policy, ODRC Policy 01-COM-11," (*Cooey*, ECF No. 817-1, PageID 17565), and;
- A "reprieve" provision stating that "[c]oncurrent with such notice to counsel, [DRC Defendants] will seek a reprieve from the Governor related to that condemned inmate's execution, *provided that* the execution is scheduled to take place less than thirty days *from the effective date* of the change in policy," (*id.* (emphases added)).

655. On or about March, 2012, DRC Defendants testified that they had implemented Incident Command Systems as part of the execution policy.

K. Defendants deviate or vary from the mandates of their written execution protocol, consistently fail to follow their informal execution policies, and falsify official documents and records.

656. The safeguards contained in Defendants' written Execution Protocol are critical to avoid violating Plaintiff's fundamental and constitutional rights in the course of an execution attempt.

657. Because the Execution Protocol must be applied in accordance with all applicable policies, administrative regulations, and statutes, the Core Elements of the Execution Protocol and their requirements must be construed subject to all applicable policies, administrative regulations, and statutes that have at least some element of overlap with those Core Elements.

658. Similarly, the Core Elements and their requirements must be construed subject to all applicable policies, administrative regulations, and statutes that have been incorporated explicitly in the Execution Protocol or implicitly through any unwritten policy or practice.

659. Accordingly, deviation from overlapping applicable policies, administrative regulations, and statutes constitutes a deviation from relevant Core Elements.

660. Likewise, deviation from applicable policies, administrative regulations, and statutes that have been incorporated explicitly in the Execution Protocol or implicitly through any unwritten policy or practice constitutes a deviation from relevant Core Elements.

661. There is substantial overlap and correlation between Core Element # 2, which establishes that "the drugs required by this policy shall be used," and the federal and Ohio state statutes and regulations related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs,

prescribing requirements, and the practice of pharmacy, medicine and/or nursing, as those federal and state statutes and regulations tightly regulate, and/or control access to, the very drugs Defendants intend to use in the Execution Protocol.

662. Alternatively, DRC Defendants have incorporated into the Execution Protocol (which is an administrative rule or regulation), as a matter of law, the Ohio state statutes and their associated regulations including, but not limited to, those related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, prescribing requirements, and the practice of pharmacy. *See Cent. Ohio Joint Vocational School Dist. Bd. of Edn. v. Ohio Bur. of Emp. Servs.*, 487 N.E.2d 288, 292 (Ohio 1986) ("[A] a rule is invalid where it clearly is in conflict with any statutory provision."); *In re Wedgewood Health Care Realty, L.L.C.*, 892 N.E.2d 960, 967 (Ohio App. 2008) ("Where an administrative rule conflicts with a legislative pronouncement, the administrative rule is invalid."); *Hoffman v. State Med. Bd. of Ohio*, 865 N.E.2d 1259, 1262 (Ohio 2007) (citation omitted) ("[A]n administrative rule may not add to or subtract from a legislative enactment . . . If it does, it creates a clear conflict with the statute, and the rule is invalid."); *Sanford v. D & T Limousine Serv., Inc.*, 671 N.E.2d 299, 304 (Ohio App. 1996) ("Any conflict, therefore, between a statute and administrative rule must be resolved in favor of the statute since administrative agencies are creatures of statute."); *State v. Vannest*, No. 94 CA 1645, 1995 WL 761453, at *4 (Ohio App. 4th Dist. Dec. 15, 1995) ("Administrative agencies possess rule-making powers pursuant to a statutory delegation of power, and an administrative rule that is issued pursuant to statutory authority generally has the

force of law. If, however, the administrative rule conflicts with a statute concerning the same subject matter, the statute takes precedence over the rule.").

663. Alternatively, DRC Defendants have incorporated into the Execution Protocol, explicitly or implicitly through their unwritten policies or practices, the Ohio state statutes and regulations including, but not limited to, those related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, prescribing requirements, and the practice of pharmacy.

664. Alternatively, DRC Defendants have incorporated into the Execution Protocol, as a matter of law under the federal Constitution's Supremacy Clause, federal statutes and regulations including, but not limited to, those related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, and prescribing requirements.

665. Alternatively, DRC Defendants have made concessions or representations that amount to unwritten or informal policies or practices incorporated into the Execution Protocol, such as DRC Defendants' recent proclamation to this Court that they have not, and will not, illegally obtain execution drugs.

666. Defendants' actions involving pentobarbital or thiopental sodium to be used under the Execution Protocol are "institutional policy" and "systemic practices" applicable to all Defendants; they are not merely individualized misconduct of poor employees or agents that cannot be fairly attributable to Defendants. *See In re: Ohio Execution Protocol Litig. (Phillips)*, No. 2:11-cv-1016, 2013 WL 5963150, 2013 U.S. Dist. LEXIS 159680, *82-84 (S.D. Ohio Nov. 7, 2013).

667. Accordingly, a violation of federal or Ohio state statutes and regulations, by or under the direction of any of the Defendants, related to Defendants' actions regarding execution drugs is a violation of Core Element # 2 that is attributable to all Defendants.

668. DRC Defendants deviate from Core Element # 2 by injecting the inmate with execution drugs that are not the concentration and/or dosage required to be used by the Execution Protocol.

669. For instance, it is substantially likely that Dennis McGuire was injected with drugs that were diluted to a concentration less than that required by 01-COM-11.

670. Defendants deviate from Core Element # 2 by using thiopental sodium as an execution drug, because using thiopental sodium violates the federal prohibition on using unapproved new drugs without a pending Investigational New Drug Application, and there is no pending IND Application to use thiopental sodium as an execution drug submitted to FDA by any Defendants.

671. Defendants deviate from Core Element # 2 by using pentobarbital as an execution drug, because using pentobarbital violates the federal prohibition on using unapproved new drugs without a pending Investigational New Drug Application, and there is no pending IND Application to use pentobarbital as an execution drug submitted to FDA by any Defendants.

672. Defendants deviate from Core Element # 2 by using imported execution drugs, because DRC Defendants have previously conceded as part of an unwritten or informal policy or practice incorporated into the Execution Protocol that they will not use imported execution drugs as part of their execution protocol.

673. Defendants deviate from Core Element # 2 by using imported thiopental sodium as an execution drug, because thiopental sodium is not a drug approved by the federal FDA and therefore it may not be legally imported into the United States.

674. Defendants deviate from Core Element # 2 by using imported pentobarbital as an execution drug to the extent that Defendants do not possess a valid registration with DEA to import pentobarbital.

675. Defendants deviate from Core Element # 2 by using imported thiopental sodium as an execution drug, to the extent such thiopental sodium was manufactured overseas in a facility not registered with the FDA, because such drug is considered "misbranded" and thus may not be legally imported into the United States.

676. Defendants deviate from Core Element # 2 by using imported pentobarbital as an execution drug, to the extent such pentobarbital was manufactured overseas in a facility not registered with the FDA, because such drug is considered "misbranded" and thus may not be legally imported into the United States.

677. Defendants deviate from Core Element # 2 by using imported pentobarbital or imported thiopental sodium as an execution drug, to the extent that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current Good Manufacturing Practices; such finished drug product would be considered adulterated under federal law, and therefore may not permissibly be manufactured, sold, delivered, or held or offered for sale under federal law.

678. Defendants deviate from Core Element # 2 by using imported pentobarbital or imported thiopental sodium as an execution drug to the extent that the finished drug

product's strength differs from, or its quality or purity falls below, applicable standards established in the United States Pharmacopeia and the national formulary; such finished drug product would be considered adulterated under federal and Ohio state law, and therefore may not permissibly be manufactured, sold, delivered, or held or offered for sale under federal and Ohio state law.

679. Defendants deviate from Core Element # 2 by using compounded pentobarbital or compounded thiopental sodium as an execution drug, because neither drug may be permissibly compounded without a valid prescription, and obtaining a valid prescription for using controlled substances such as pentobarbital or thiopental sodium as an execution drug is impossible under federal and Ohio law. A prerequisite for a prescription for a controlled substance to be valid under federal law is that the order must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. An order purporting to be a prescription that was not issued in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription under federal law. And under Ohio law, a prescription, to be valid, must also be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a valid prescription under Ohio law.

680. Defendants deviate from Core Element # 2 by using adulterated thiopental sodium as an execution drug, because DRC Defendants have conceded as part of an unwritten or

informal policy or practice incorporated into the Execution Protocol that they will not use adulterated thiopental sodium as part of their execution protocol.

681. Defendants deviate from Core Element # 2 by using compounded pentobarbital or compounded thiopental sodium as an execution drug to the extent that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current Good Manufacturing Practices; such finished drug product would be considered adulterated under federal law, and therefore may not permissibly be manufactured, sold, delivered, or held or offered for sale under federal law.

682. Defendants deviate from Core Element # 2 by using compounded pentobarbital or compounded thiopental sodium as an execution drug to the extent that the finished drug product's strength differs from, or its quality or purity falls below, certain standards established in the United States Pharmacopeia and the national formulary; such finished drug product would be considered adulterated under federal and Ohio state law, and therefore may not permissibly be manufactured, sold, delivered, or held or offered for sale under federal and Ohio state law.

683. Defendants deviate from Core Element # 2 by using compounded pentobarbital or compounded thiopental sodium as an execution drug, because either compounded drug product would be considered dangerous to health or health-endangering when used as "prescribed" to execute Plaintiff, and therefore characterized as "misbranded" under federal law and Ohio law, and therefore may not permissibly be manufactured, sold, delivered, or held or offered for sale under federal and Ohio state law.

684. Defendants deviate from Core Element # 2 by using compounded pentobarbital or compounded thiopental sodium as an execution drug if it is compounded by a so-called 503A Compounding Pharmacist; under federal and Ohio state law, a 503A Compounding Pharmacy may only compound or dispense a compounded product pursuant to a valid prescription order or a notation on a valid prescription order that a compounded product is necessary for the identified patient. Because a drug used to kill Plaintiff can never be said to be "necessary" for him under the law, a 503A Compounding Pharmacist would not have a legitimate prescription or notation from a prescribing practitioner of the necessity for a compounded drug, and thus could not prepare and dispense drugs to be used for a lethal-injection execution while remaining in compliance with federal and Ohio state law.

685. Defendants deviate from Core Element # 2 by using compounded pentobarbital as an execution drug if it is compounded by a so-called 503B Outsourcing Facility; a 503B Outsourcing Facility is prohibited from producing drug products that are "essentially a copy of an approved drug," such as pentobarbital.

686. Defendants deviate from Core Element # 2 by using expired execution drugs, including drugs that are past their "beyond-use" date, because DRC Defendants have conceded as part of an unwritten or informal policy or practice incorporated into the Execution Protocol that they will not use expired execution drugs as part of their execution protocol.

687. Defendants deviate from Core Element # 2 by using non-sterile, impure, contaminated, adulterated, misbranded or illegally obtained execution drugs because

the Execution Protocol does not allow for use of non-sterile, impure, contaminated, adulterated, misbranded or illegally obtained execution drugs.

688. Defendants deviate from Core Element # 2 by using compounded drugs that have not been compounded in full compliance with USP 797, and therefore are compounded in violation of Ohio law, including the requirements for analytical testing of purity, sterility, the presence of pyrogens and other potential contaminants, and other prophylactic measures that make strict compliance with USP 797 so demanding.

689. Defendants deviate from Core Element # 2 by using execution drugs that are not the exact type of drug, in the quantities and concentrations mandated in the written protocol, because the written protocol does not allow for use of any execution drugs other than the specific type of drug in the specific quantities and concentrations mandated in the Execution Protocol.

690. For all of the reasons identified above by which Defendants deviate from Core Element # 2, they also deviate from Core Elements # 1 and # 3.

691. This is because Core Elements # 1 and # 3 require that Medical Team Members who administer the drugs to Plaintiff for his execution must "be authorized to administer drugs under Ohio law," and, with respect to the "functions" such Medical Team Members are required to perform, they must be "medically-qualified persons."

692. Any authorization any such Medical Team Members may possess to "administer drugs under Ohio law" includes, as a minimum requirement, express or implied, that their administration of such drugs not be in violation of Ohio law or federal law. None of the Medical Team Members does or can meet that requirement if and to the extent any of the deviations identified above with respect to Core Element # 2 exist

for any particular execution. Each of the Medical Team Members exceeds, and therefore violates, his/her authorization to administer drugs under Ohio law in the circumstance of any execution in which any of the deviations identified above with respect to Core Element # 2 exist.

693. Similarly, any qualifications any of the Medical Team Members may possess to perform the medical functions they are required to perform in an execution under the Execution Protocol include, as a minimum qualification, express or implied, that their performance of their medical functions complies with all governing and applicable laws and regulations, including the applicable ethics standards and applicable professional standards of practice. When the performance of a medical function under the Execution Protocol violates federal and/or Ohio law or applicable ethics or professional practice standards, there is no Medical Team Member who is "medically-qualified" to perform that function. The performance by a Medical Team Member of a medical function under the Execution Protocol, where the performance of that function is in violation of federal and/or Ohio law or applicable ethics or professional practice standards, is a medical function that no Medical Team Member is medically-qualified to perform. No Medical Team Member is medically-qualified to perform any medical function whose performance involves any of the deviations identified above with respect to Core Element # 2.

694. DRC Defendants deviate from Core Element # 5 on every occasion when they prematurely take actions under 01-COM-11 that are not supposed to occur until death has occurred, and when they fail to take actions required to be done until the prisoner is dead, such as those actions required by ¶¶ VI.H.1.g-h (p. 15/19), or ¶¶ I (p. 17-18),

and there is no record of the Director's written authorization to engage in such deviations.

695. For example, it is substantially likely that Dennis McGuire was still clinically and statutorily alive when DRC Defendants took actions under 01-COM-11 to declare him dead, and when they took other actions that followed. Each of those actions was a deviation from 01-COM-11.

696. Thus, DRC Defendants acted to close the curtain to the Death Chamber and to evaluate McGuire by the "appropriate medical professional" to "confirm death" before "the completion of the process," in deviation from ¶¶ VI.H.1.h.

697. There is no evidence that the Director authorized that deviation in any way, and certainly no evidence that the Director authorized that deviation in writing.

698. DRC Defendants likewise acted before "a sufficient time for death to have occurred" when they closed the curtain ten minutes after injection, and when they took subsequent actions as to Dennis McGuire, also in deviation from 01-COM-11's provisions, without any prior written authorization for those deviations from the Director.

699. These and other deviations and/or variations have occurred under several different effective versions of the written protocol, including the written protocols in effect before November 30, 2009, and the protocols effective November 30, 2009; November 14, 2010; March 9, 2011; April 11, 2011; September 18, 2011; and October 10, 2013.

700. DRC Defendants consistently and regularly deviate or vary from their execution policy and written protocol in numerous ways, big and small, such that DRC

Defendants have a long-standing pattern of deviations and/or variations from their execution policy and written execution protocol.

701. DRC Defendants' pattern of deviations and/or variations continues to this day. Ohio has a lengthy execution schedule. Each execution process presents yet another opportunity for Defendants to deviate from their Execution Protocol.

702. The record in this case is replete with evidence of Defendants deviating or varying from the mandates of their written execution protocol and from their information execution policies. *See, e.g.*, *Cooey v. Kasich (Kenneth Smith)*, 801 F. Supp. 2d 623, 625-52 (S.D. Ohio 2011), factual findings contained therein alleged here by reference (relevant excerpts attached as **Exhibit 3**); *In re Ohio Execution Protocol Litigation (Charles Lorraine)*, 840 F. Supp. 2d 1044, 1055-59 (S.D. Ohio 2012) (same) (relevant excerpts attached as **Exhibit 4**); Amended Omnibus Compl., Doc. 158, ¶728-790, allegations incorporated here by reference (relevant excerpts attached as **Exhibit 5**).

703. This includes deviations from core requirements of the written protocol, as well as deviations which were core deviations because they were unauthorized deviations from non-core elements of the written protocol.

704. By these deviations and/or variations, Defendants ignore and/or recklessly disregard their execution policy's and written protocol's requirements.

705. Defendants' pattern of deviations and/or variations from their execution policy and written execution protocol means that Defendants will arbitrarily and irrationally administer their execution policy and written execution protocol differently each time they execute an inmate.

706. There are no legitimate governmental or penological reasons for these deviations and/or variations.

707. Defendants' deviations and/or variations are not necessary to achieve a compelling governmental interest.

708. DRC Defendants rely on ICS to immunize their execution method from constitutional challenge.

709. But DRC Defendants do not strictly comply with the tasks and requirements established by their use of ICS as part of the execution policy.

710. The veracity of the documents and records DRC Defendants create that purport to demonstrate strict compliance with the written execution protocol and informal execution policies is undermined by evidence of falsification of official records and documents, and by official records and documents that do not accurately reflect the proceedings that occurred or that seek to sanitize such proceedings.

711. This includes the falsification and/or sanitization and/or incomplete character of official records and documents related to significant events involving inmates in DRC Defendants' control and subject to DRC Defendants' procedures.

712. DRC Defendants or their agents falsified official records and documents following the suicide of former Plaintiff Billy Slagle during the "First Operational Period" of DRC Defendants' administration of 01-COM-11 to Slagle.

713. Following Slagle's suicide, DRC Defendants claimed to have previously had in place a policy to facilitate attorney-client communication and access at all times, when no such policy existed at that time.

714. The official After-Action Review and other related documentation produced in accordance with DRC Defendants' alleged implementation of ICS for administering 01-COM-11 to Slagle contains falsehoods and misrepresentations.

715. Upon information and belief, the evidence of actions DRC Defendants took related to Slagle's suicide does not comport with the actions required under the relevant ICS documentation.

716. Official records and documents were falsified following the suicide of inmate Ariel Castro while in custody and control of DRC.

717. Spurious allegations about Castro—which might have placed the DRC Defendants and their agents in a better light—were included in an official report that had no basis in fact.

718. Investigators conducting the "investigation" into matters related to the execution of Dennis McGuire were not independent investigators at all, but rather two attorneys from the same division of the Ohio Attorney General's Office that represents DRC Defendants in this litigation.

719. Yet the public impression DRC Defendants conveyed was that the investigation was an independent investigation.

720. The investigators entire "investigation" regarding the McGuire execution consisted of interviewing DRC employees (who, by the virtue of their employment as Defendants in this litigation and/or as DRC employees had a vested interest in minimizing the official account of what happened during that execution) and asking leading questions about what those employees witnessed.

721. Upon information and belief, the "investigators" interviewed no independent witnesses of the McGuire execution as part of the "investigation," nor did "investigators" interview any of the witnesses present on behalf of McGuire.

722. Nevertheless, the April 28, 2014 After-Action Review and Executive Summary related to the execution of McGuire strongly and repeatedly implies that investigators interviewed witnesses other than DRC employees.

723. The same report significantly downplays the description of what occurred in the Death Chamber during the execution of McGuire.

724. The same report implies that DRC Defendants and/or their counsel and/or the "investigators" from the Attorney General's Office corresponded and consulted with Dr. Dershwitz to reach their findings and recommendations. But that is not true.

725. DRC Defendants and/or their agents wrongly and misleadingly suggested that Dr. David Waisel "recommended" an execution method, and that DRC Defendants adopted their 2014 Execution Protocol based on that purported "recommendation," but Dr. Waisel emphatically did NOT in any way offer any recommendation, endorsement, suggestion, or anything else as to Defendants' new execution protocol.

726. The Execution Timeline log that purportedly contains all significant events that took place during McGuire's execution lacks any entry describing the horrific spectacle that unfolded in the Death Chamber following injection of the execution drugs.

727. The ICS documents created related to the McGuire execution falsely give the impression that there was nothing out of the ordinary that occurred during that execution.

L. Allegations involving examples of specific, relevant executions or execution attempts.

Dennis McGuire

728. Defendants were warned on numerous occasions in advance of Dennis McGuire's January 16, 2014 execution of the substantial likelihood that McGuire's body habitus presented a substantial likelihood that McGuire would obstruct and suffocate if subjected to Defendants' execution protocol.

729. Despite numerous warnings by McGuire's counsel and expert witness, the physical assessments carried out pursuant to Defendants' execution protocol affirmatively stated that there were no problems that might affect the execution, and/or failed to note any possible problems that might affect the execution.

730. Despite significant warnings of impending problems with McGuire's execution, Defendants took no actions to have any kind of resuscitative measures on hand or in place in the Death House before they proceeded with the execution.

731. Defendant Mohr and/or Defendant Gray explicitly confirmed just minutes before starting the execution of McGuire that Defendants had not put into place any kind of resuscitative measures and had no plan to do so for McGuire's execution.

732. Approximately 26 minutes elapsed between the time when Defendants injected McGuire and when Defendant Warden Morgan declared the time of death.

733. A death occurring over approximately 26 minutes is a lingering death.

734. There is a substantial risk that McGuire remained clinically and statutorily alive at the time Defendant Warden Morgan declared him dead.

735. There is a substantial risk that McGuire remained clinically alive for as long as 45 more minutes after the Warden announced a time of death.

736. A death occurring over approximately 70 minutes is a lingering death.

737. Even assuming that McGuire was clinically and statutorily dead at the time Defendant Warden Morgan declared him dead, McGuire suffered a lingering death as a result of Defendants' application of 01-COM-11.

738. Descriptions of the scene in the death chamber during following Defendants' injection into McGuire of midazolam and hydromorphone characterized the scene as "ghastly," disturbing, inhumane, and horrendous. As one witness described the scene: "he was fighting for breath, and I could see both of his fists were clenched the entire time. His gasps could be heard through the glass wall that separated us. Towards the end, the gasping faded into small puffs of his mouth. It was much like a fish lying along the shore puffing for that one gasp of air that would allow it to breathe." Lawrence Hummer, "*I witnessed Ohio's execution of Dennis McGuire. What I saw was inhumane,*" The Guardian (January 22, 2014).[9]

739. McGuire's death was a spectacle, undignified, disgraceful execution as a result of Defendants' 01-COM-11, as written and as applied to him.

740. Despite these objective descriptions, Defendants' formal paperwork related to the McGuire execution fails to acknowledge the spectacle that unfolded in the death chamber.

741. The "Timeline Log" that is supposed to document everything significant that occurs during Defendants' execution process contains no entries describing what occurred in

[9]Available at http://www.theguardian.com/commentisfree/2014/jan/22/ohio-mcguire-execution-untested-lethal-injection-inhumane.

the death chamber between the time when the continuous flush of saline solution started at 10:28:28 and when Drug Administrator # 23 entered the death chamber to "make an assessment" of McGuire at 10:48:47.

742. The After-Action Review document completed on January 16, 2014 immediately following the McGuire execution included the question "Were there acts or events that were identified in advance as anticipated contingencies; if so, did those things occur?" The official answer in the January 16, 2014 After-Action Review was "No."

743. The January 16, 2014 After-Action Review included the following question: "Were there acts or events that were not anticipated in advance?" Answer: "No."

744. The January 16, 2014 After-Action Review included the following question: "How well did the process work? Should changes to the process be considered?" Answer: "The process worked very well and the execution was carried out in compliance with 01-COM-11."

745. The "Executive Summary" completed on April 28, 2014 regarding McGuire execution asserts that McGuire's execution was "humane, dignified and [done in a] lawful manner."

746. The Executive Summary allowed only that "[s]everal minutes after the administration of the[] drugs, McGuire appeared to be unconscious and exhibited some irregular movements in his abdomen and mouth," while subsequently reasserting that Defendants "remain[] confident in [their] belief that the McGuire execution was carried out consistent with DRC's policies and constitutional requirements."

747. The "After-Action Review" completed on April 28, 2014 also asserted that McGuire "was not conscious beginning a few minutes after the drugs were administered. He

did not experience pain, distress or air hunger after the drugs were administered or when the bodily movements and sounds occurred. Therefore, his execution was conducted in a constitutional manner consistent with the Policy."

748. Upon information and belief, the persons who conducted the "investigation" into the McGuire execution have previously been involved in defending this case or similar cases.

749. Upon information and belief, the "investigators" spoke only with DRC employees, including some Defendants and Defendants' expert witness, Dr. Dershwitz, in the course of their "investigation." They did not speak to other third-party eyewitnesses.

Joseph Wood

750. On July 23, 2014, the State of Arizona used an execution protocol entailing IV injection of 50 mg. midazolam and 50 mg. hydromorphone to execute Joseph Wood.

751. Upon information and belief, Arizona's execution protocol was adopted after Arizona officials' consideration of Ohio's execution protocol used to execute McGuire.

752. The execution of Wood lasted almost two hours between the start of the first injection and when Wood was pronounced dead.

753. During that two hours, Wood suffocated to death in a procedure that Senator John McCain described as a "bollocks-upped situation" that "[was] torture." Burgess Everett, "John McCain: Arizona execution 'torture'", Politico, July 24, 2014.[10]

[10]Available at http://www.politico.com/story/2014/07/john-mccain-arizona-execution-109350.

754. One witness to the execution described Wood as "drowning in air," as suffering "death by apnea," and as gasping for air at least 640 times: Wood "gulped like a fish on land. The movement was like a piston: The mouth opened, the chest rose, the stomach convulsed. And when the doctor came in to check on his consciousness and turned on the microphone to announce that Wood was still sedated, we could hear the sound he was making: a snoring, sucking, similar to when a swimming-pool filter starts taking in air, a louder noise than I can imitate, though I have tried." Michael Kiefer, "*Reporter describes Arizona execution: 2 hours, 640 gasps*," Arizona Republic, July 26, 2014.[11]

755. Arizona officials injected Wood with fifteen syringes of the midazolam/hydromorphone mixture over the course of the execution, meaning Wood was injected with a total of 750 mg. of hydromorphone and 750 mg. of midazolam.

Clayton Lockett

756. On April 14, 2014, the State of Oklahoma adopted a new execution protocol that included the use of IV injection of 100 mg. midazolam as the first of a three-drug injection sequence.

757. On April 29, 2014, the State of Oklahoma executed Clayton Lockett using what is believed to be an execution protocol including IV injection of 100 mg. midazolam. Lockett was not declared dead until 43 minutes after the start of his execution.

[11] Available at http://www.azcentral.com/story/news/arizona/politics/2014/07/24/arizona-execution-joseph-wood-eyewitness/13083637/.

758. Ohio was directly involved in the Lockett execution because, following the McGuire execution, the "General Counsel in Ohio" provided advice to officials in Oklahoma, encouraging Oklahoma's use of midazolam as an execution drug and downplaying any concerns from Ohio's experience during the McGuire execution. *See Warner v. Gross*, Case No. 5:14-cv-665, ECF No. 159, Plaintiffs' Proposed Findings of Fact and Conclusions of Law, at p. 8-9 of 83 (W.D. Okla. Dec. 12, 2014).

759. According to Michael Oakley, the General Counsel for Oklahoma's Department of Corrections at or around the time Oklahoma adopted its execution protocol that included midazolam, "General Counsel in Ohio" consulted with him about midazolam after Ohio executed McGuire. *Id.*

760. So rather than warn others about the horrifying scene that was likely to unfold if a state used drugs in a lethal-injection execution similar to what Defendants had recently experienced with the McGuire execution, Defendants downplayed and discounted what occurred during the McGuire execution in consultation with officials in other states who were considering following Ohio's lead.

761. The execution of Lockett was painful, lingering, undignified and inhumane, as Lockett struggled, writhed, grimaced, kicked, bucked, shook, arched his back, tried to sit up, jerked, and gasped, even after he was allegedly "unconscious." *See generally, id.* at p. 10-44 of 83 (describing the horrific scene that unfolded during Lockett's execution); *see also* Cary Aspinwall & Ziva Branstetter, Botched execution described

as 'a bloody mess,' court filing shows, Tulsa World, December 14, 2014[12]; Katie Fretland, Scene at botched Oklahoma execution of Clayton Lockett was 'a bloody mess,' The Guardian, Dec. 13, 2014[13].

762. Oklahoma officials who participated in or witnessed the execution described the scene as "like a horror movie," and that "shit's fucking with me." *Warner v. Gross, supra*, Plaintiffs' Proposed Findings of Fact and Conclusions of Law, at p. 43 of 83. A member of the execution team described the entire Lockett execution as a "cluster." *Id.*

Kelly Gissendaner

763. On or about March 2, 2015, the State of Georgia intended to execute Kelly Gissendaner using compounded pentobarbital, but ultimately postponed the execution because of problems with the compounded pentobarbital.

764. The pentobarbital to be used was sent to an independent testing laboratory, tested for potency and identity, and given a report that the drug was within the acceptable testing limits. *See* Tracy Connor, *Georgia Execution of Kelly Gissendaner Postponed for Drug Issue*, Mar. 3, 2015[14]; Chris McDaniel, *Georgia Says "Cloudy" Execution*

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[12] Available at http://m.tulsaworld.com/news/investigations/botched-execution-described-as-a-cluster-court-filing-shows/article_a4b70b76-84f7-5ebd-a5f3-044c205d474a.html?mode=jqm.

[13] Available at http://www.theguardian.com/world/2014/dec/13/botched-oklahoma-execution-clayton-lockett-bloody-mess.

[14] Available at http://www.nbcnews.com/news/us-news/georgia-execution-kelly-gissendaner-postponed-drug-issue-n315651.

Drug Was Just Too Cold, But Expert Gave A Second Possible Reason, May 11, 2015[15].

765. Despite passing the analytical testing that may mirror Defendants' Execution Protocol testing, the compounded pentobarbital precipitated, or developed particles floating in the drug.

766. The particulate in the compounded pentobarbital would have likely caused an unacceptable pH level in the final product which, in turn, would have caused severe pain upon being injected.

767. Being compounded using incorrect compounding techniques or materials have been identified as a possible cause for the precipitation.

768. Being shipped and/or stored at a temperature that was too low has also been identified as a possible cause for the precipitation.

769. Nothing in Defendants' Execution Protocol would prevent Defendants from using precipitated drugs in an execution in the same kind of circumstances, as the Gissendaner drugs had "passed" the analytical testing Defendants offer.

Michael Lee Wilson

770. On January 10, 2014, the State of Oklahoma executed Michael Lee Wilson using what is believed to be IV injection of compounded pentobarbital. *See* Graham Lee

[15] Available at http://www.buzzfeed.com/chrismcdaniel/georgia-says-cloudy-execution-drug-was-just-too-cold-but-exp#.cpqe8DRX5.

Brewer, *Condemned man's last words lead to questions about lethal injection 'cocktail' in Oklahoma, U.S.*, The Oklahoman, Feb. 9, 2014.[16]

771. Approximately twenty seconds after being injected with the execution drugs, Wilson stated "I feel my whole body burning." *Id.*

772. When pentobarbital is compounded from its raw API form to an injectable liquid, an incorrect compounding procedure will produce inappropriate pH levels which, when injected into the bloodstream, will cause intense burning pain.

Arnold Preito

773. Recent executions in Texas using what is believed to be compounded pentobarbital have taken significantly longer before death was declared than previous executions using manufactured, FDA-approved pentobarbital.

774. Texas implemented a one-drug pentobarbital lethal-injection protocol on July 18, 2012, using FDA-approved pentobarbital. Death Penalty Information Center, *State by State Lethal Injection*, http://www.deathpenaltyinfo.org/state-lethal-injection.

775. Under that protocol, it took 12 minutes until Bobby Hines was declared dead on October 24, 2012. *Texas executes convicted killer for 1991 slaying*, Associated Press, Oct. 24, 2012, http://newsok.com/texas-executes-convicted-killer-for-1991-slaying/article/feed/452560.

[16] Available at http://newsok.com/condemned-mans-last-words-lead-to-questions-about-lethal-injection-cocktail-in-oklahoma-u.s./article/3932043.

776. But numerous executions have taken significantly longer since Texas began using pentobarbital from a compounding pharmacy in October, 2013. Death Penalty Information Center, *State by State Lethal Injection*, *supra*.

777. On January 21, 2015, it took at least 20 minutes before Arnold Prieto was declared dead from a lethal-injection using compounded pentobarbital. Michelle Casady, *Killer of 3 executed, decades after turning down 30-year plea deal*, mysanantonio.com, Jan. 21, 2015.[17].

Kent Sprouse

778. On April 9, 2015, it took at least 22 minutes before Kent Sprouse was declared dead from a lethal-injection using compounded pentobarbital. *Texas Executes Man for Police Officer's 2002 Shooting Death*, Associated Press, Apr. 9, 2015.[18]

Manuel Garza

779. On April 15, 2015, it took at least 26 minutes before Manuel Garza was declared dead from a lethal-injection using compounded pentobarbital. Michael Graczyk, *Texas executes San Antonio man for killing police officer*, Associated Press, Apr. 15, 2015, http://bigstory.ap.org/article/467586558ac3423b86d7c450c9c61882/man-set-be-executed-killing-san-antonio-officer (last visited Sept. 4, 2015).

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[17] Available at http://www.mysanantonio.com/news/local/crime/article/Convicted-killer-set-to-die-tonight-turned-down-6030235.php.

[18] Available at http://www.nytimes.com/aponline/2015/04/09/us/ap-us-texas-execution.html?_r=0.

Derrick Charles

780. On May 12, 2015, it took at least 25 minutes before Derrick Charles was declared dead from a lethal-injection using compounded pentobarbital. Michael Graczyk, *Texas executes Houston man convicted of killing his girlfriend, her mother and her grandfather*, Associated Press, May 12, 2015.[19]

Gregory Russeau

781. On June 18, 2015, it took at least 21 minutes before Gregory Russeau was declared dead from a lethal-injection using compounded pentobarbital. *Texas executes man for murdering auto shop owner during crack cocaine binge*, Associated Press, June 18, 2015.[20]

Jose Villegas

782. On April 16, 2014, the State of Texas executed Jose Villegas, using what is believed to be compounded pentobarbital.

783. After the injection started, Villegas is reported to have said "It does kind of burn." Associated Press, "'It does kind of burn,' Texas inmate Jose Villegas says as he gets lethal injection for murders of 3," Associated Press (April 15, 2014).[21]

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[19] Available at http://globalnews.ca/news/1995091/texas-executes-houston-man-convicted-of-killing-his-girlfriend-her-mother-and-her-grandfather/.

[20] Available at http://www.dallasnews.com/news/state/headlines/20150618-texas-executes-man-for-murdering-auto-shop-owner-during-crack-cocaine-binge.ece.

[21] Available at http://www.nola.com/news/index.ssf/2014/04/it_does_kind_of_burn_texas_inm.html.

Eric Robert

784. On or about October 16, 2012, the State of South Dakota executed Eric Robert, using compounded pentobarbital that post-execution analysis revealed was contaminated with fungus.

785. After the injection started, Robert reportedly "appeared to be clearing his throat and then began gasping heavily. He then snored for about 30 seconds. His eyes remained opened throughout and his skin turned pale, eventually gaining a purplish hue." Dave Kolpack and Kristi Eaton, "*Eric Robert Execution: South Dakota Executes Inmate Who Killed Prison Guard*," Associated Press, October 16, 2012.[22]

786. Robert's eyes remained open throughout his execution. That fact, according to some experts, is a sign that the compounded execution drugs did not work properly. Stephanie Mencimer, "*Does This Secret Drug Cocktail Work To Execute People? Oklahoma Will Find Out Tonight*," Mother Jones, April 29, 2014.[23]

787. Robert was not declared dead until twenty minutes following injection of the compounded pentobarbital.

788. This is consistent with being injected with sub-potent pentobarbital.

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[22]Available at http://www.huffingtonpost.com/2012/10/16/eric-robert-execution_n_1969640.html.

[23]Available at http://www.motherjones.com/mojo/2014/04/double-execution-tonight-ok-using-secret-experimental-drug-protocol.

FEDERAL LAW CLAIMS FOR RELIEF AGAINST DRC DEFENDANTS IN THEIR OFFICIAL CAPACITIES AND DRUG SOURCE DEFENDANTS

First Cause of Action: Eighth and Fourteenth Amendment Violations

789. The First Cause of Action has been withdrawn from this Third Amended Omnibus Complaint, to be, as applicable, re-alleged in parts or in whole in the various Plaintiffs' Amended Individual Supplemental Complaint.

Second Cause of Action: Fourteenth Amendment Due Process Violations

790. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

791. An execution carried out using the drugs contemplated in the Execution Protocol will not be "quick," nor will it be "painless," physically and/or mentally.

792. Defendants are aware that an execution using the Plan 1 or Plan 2 drugs will almost certainly take more than thirty minutes following the injection of the execution drugs until the inmate is dead in accordance with Ohio law set forth in Ohio Revised Code § 2108.40, but they willingly and knowingly disregard this risk.

793. Defendants are aware than an execution using Plan 1 or Plan 2 drugs will produce a lingering death as the condemned inmate slowly suffocates to death or suffers a heart attack over a period that is likely to be 10-15 minutes or more, but they willingly and knowingly disregard this risk.

794. Defendants are aware that an execution using improperly compounded drug(s) will subject the condemned inmate to painful burning sensations upon injection intravenously, and they are aware of the significant risk of obtaining improperly

compounded drug(s) to use in an execution, but they willingly and knowingly disregard this risk.

795. Defendants are aware that at least a not-insignificant number of Plaintiffs possess individual mental/psychological conditions and characteristics which make such Plaintiffs substantially likely to suffer from a paradoxical effect upon injection of the Plan 1 or Plan 2 drugs, but they willingly and knowingly disregard this risk.

796. DRC Defendants have created, maintained, and administered an overarching execution policy and written execution protocol that, if used to execute Plaintiff's death sentence, will violate his constitutionally protected liberty, life, and property interests (as arising from Ohio Rev. Code § 2949.22(A) and DRC Policy 01-COM-11) in expecting and receiving a "quick and painless death" and/or a humane and dignified execution.

797. Ohio Revised Code § 2949.22(A) creates valid liberty, life, and property interests vested in Plaintiff in expecting a "quick and painless" death.

798. Ohio Revised Code § 2949.22(A) also creates valid liberty, life, and property interests vested in Plaintiff in receiving a "quick and painless" death.

799. DRC Policy 01-COM-11 is binding state law, and creates valid liberty, life, and property interests vested in Plaintiff in expecting a humane and dignified death.

800. DRC Policy 01-COM-11 is binding state law, and creates valid liberty, life, and property interests vested in Plaintiff in receiving a humane and dignified death.

801. These interests are rights vested in a small class of individuals that have a legitimate claim of entitlement to expect and receive a quick, painless, humane and dignified death.

802. Plaintiff, as a death row inmate, is a member of the only group that is the intended beneficiary of these guarantees.

803. Under the express terms of § 2949.22(A) and DRC Policy 01-COM-11, Defendants have no discretion in whether to provide a quick, painless, humane and dignified death to Plaintiff or some kind of death other than a quick, painless, humane and dignified one.

804. These interests arising under state law are protected as rights under the substantive and procedural elements of the Due Process Clause of the Fourteenth Amendment.

805. Defendants, having granted Plaintiff interests in expecting and receiving a quick, painless, humane and dignified execution, may not deprive him of those rights in violation of procedural and substantive due process under the Fourteenth Amendment.

806. Defendants' denial of Plaintiff's rights to expect and receive a quick, painless, humane and dignified death is arbitrary and conscience-shocking.

807. The pattern of deviations and/or variations from Defendants' execution policy and written execution protocol engaged in by many of the actors involved, intentional or otherwise, combined with the amount of discretion that Defendants claim under their overarching execution policy and under the written protocol, along with substantial evidence of incompetence or inability to perform in the execution context, cumulatively point to an unacceptable risk of violating Plaintiff's rights.

808. By what DRC Defendants include and exclude from their overarching execution policy—including their contemplated use of execution drugs manufactured and/or otherwise supplied by the Drug Source Defendants using compounding or illegally

imported or otherwise sourced drugs, their intended use of the specific drugs in Plan 1 and Plan 2, and their continued refusal to adequately prepare for and provide medical assistance as necessary in the execution context, even with full notice of that necessity—their development of the written execution protocol, their discretionary and faulty administration of the execution policy, and their willingness to shade or color the official record to keep secret critical details about an execution and those who acted outside the law to facilitate it, Defendants manifest deliberate indifference towards, or intentional deprivation of, Plaintiff's statutorily created liberty, life, and property interests in expecting and receiving a quick, painless, humane and dignified death, interests protected as rights by the substantive and procedural elements of the Fourteenth Amendment's Due Process Clause.

809. These rights are separate and distinct from the rights protecting Plaintiff against cruel and unusual punishment as provided in the Eighth Amendment.

810. In all the foregoing ways, Defendants violate 42 U.S.C. § 1983 and Plaintiff's rights protected by the Fourteenth Amendment to the United States Constitution.

Third Cause of Action: Violations of First, Sixth, Eighth and Fourteenth Amendment Rights of Access to Counsel, Access to Courts, Ability to Petition for Redress of Grievances, Due Process, and Privileges or Immunities of United States Citizenship.

811. The Third Cause of Action is withdrawn.

Fourth Cause of Action: Fourteenth Amendment Equal Protection Violations

812. As to each of the Equal Protection Clause violations alleged below, Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

813. Plaintiff has been or will be treated differently from other similarly situated individuals, burdening his fundamental rights as a member of a class of persons, without a compelling governmental interest, and/or without any rational basis for the difference in treatment as a class of one irrationally and arbitrarily, in violation of the guarantees of the Equal Protection Clause of the Fourteenth Amendment.

814. Defendants violate Plaintiff's rights under the Equal Protection Clause of the Fourteenth Amendment to the federal Constitution by their Execution Protocol as written, and by their actions in applying the Execution Protocol and other binding federal and Ohio state laws relevant here.

815. Equal protection under the law requires "minimal procedural safeguards" such that there is at least some assurance that the rudimentary requirements of equal treatment and fundamental fairness are satisfied.

816. The Equal Protection Clause's rudimentary requirements are important here, where the Supreme Court has clearly emphasized the necessity of procedural safeguards in a state's lethal injection execution policy, especially including the written protocol, to ensure against violations of fundamental rights.

817. DRC Defendants' execution policy and written execution protocol is facially violative of the Equal Protection Clause, because it codifies disparate treatment of similarly

situated individuals, without sufficient justification, and in a way that is arbitrary, irrational, and capricious.

818. DRC Defendants have shown an ongoing inability to consistently adhere to their Execution Protocol, resulting in the disparate treatment of Plaintiff during his execution compared to similarly situated inmates. *See Cooey v. Kasich*, 801 F. Supp. 2d 623, 656 (S.D. Ohio 2011) ("The perplexing if not often shocking departures from the core components of the execution process that are set forth in the written protocol not only offend the Constitution based on irrationality but also disturb fundamental rights that the law bestows on every individual under the Constitution, regardless of the depraved nature of his or her crimes.")

A. Equal Protection—Fundamental Rights

819. Plaintiff, individually and as a member of a class of persons subject to a death sentence under Ohio law, has fundamental rights under the Eighth Amendment to be free from cruel and unusual punishment, to not be subject to a torturous, horrifying, lingering, undignified, or spectacular death, and to be provided necessary medical care by Defendants.

820. Plaintiff, individually and as a member of a class of persons subject to a death sentence under Ohio law, has individual fundamental rights to privacy, to personal dignity, to bodily integrity, to not be the unwilling subject of forced, involuntary human experimentation conducted by Defendants, and others that arise under the principles of liberty and/or natural law, and which are protected by the Ninth Amendment.

821. Plaintiff, individually and as member of a class of persons subject to a death sentence under Ohio law, has fundamental rights to the protections afforded by the substantive and procedural elements of the Due Process Clause of the Fourteenth Amendment, which protect as rights created by the State in § 2949.22 Plaintiff's life, liberty and property interests in expecting and receiving a quick and painless execution; rights created by the State in the Execution Protocol's mandate that "all execution processes shall be performed in a professional, humane, sensitive, and dignified manner" Plaintiff's life, liberty and property interests in expecting and receiving a humane, sensitive and dignified execution; and Plaintiff's right to due process in the form of notice of how Defendants will attempt to execute him.

822. Plaintiff, individually and as member of a class of persons subject to a death sentence under Ohio law, has fundamental rights under the Due Process Clause of the Fourteenth Amendment to the liberty and privacy right one has in the integrity of one's body, as well as to not be the unwilling, non-consenting subject of human experimentation, and to be free from government conduct that is shocking to the conscience.

823. Plaintiff, individually and as member of a class of persons subject to a death sentence under Ohio law, has a fundamental right under the Privileges or Immunities Clause of the Fourteenth Amendment to not be the unwilling, non-consenting subject of human experimentation.

824. Carrying out an execution is not a compelling governmental interest.

825. Carrying out an execution at all costs is neither a compelling governmental interest nor a legitimate governmental interest.

1. Equal Protection violation based on burdening of Plaintiff's fundamental rights by Defendants' deviations from the Execution Protocol.

826. Plaintiff is similarly situated to other condemned inmates to whom Defendants will apply their execution protocol.

827. In their application of their Execution Protocol, including in their deviations and/or their variations from their execution policy and written Execution Protocol, including their deviations from Core Elements of the Execution Protocol as alleged throughout this Third Amended Omnibus Complaint, Defendants are violating the Equal Protection Clause's guarantee of equal treatment for similarly situated persons by severely burdening Plaintiff's fundamental rights through increasing the likelihood that Plaintiff will:

(1) be denied the Eighth Amendment rights to be given necessary medical care while in DRC Defendants' custody, and to be free from a substantial risk of serious harm, including physical and/or psychological pain, needless suffering, a torturous, lingering, undignified, or spectacular death, and/or an objectively intolerable risk of such harm which Defendants unjustifiably ignore;

(2) suffer deprivation of his fundamental rights to privacy, to personal dignity, to bodily integrity, and to not be the unwilling, non-consenting subject of forced, involuntary human experimentation conducted by Defendants, as protected by the Ninth Amendment, the Fourteenth Amendment's Due Process Clause, or the Fourteenth Amendment's Privileges or Immunities Clause, as demonstrated during the botched executions of Joseph Clark, Christopher Newton, Dennis McGuire, and others, the failed execution of Romell Broom,

and the experimental—but secretive—approach to executions with which Defendants now operate;

(3) not be free from suffering conscience-shocking, arbitrary and lawless actions by Defendants that increase the harm to which he will be subjected, in violation of the Fourteenth Amendment;

(4) be forced to suffer expecting and receiving an execution that is something other than quick and painless, be denied the expectation and receipt of an execution that is humane, and be denied the expectation and receipt of an execution that is dignified, protected by the Fourteenth Amendment; or

(5) be denied the chance to know sufficiently in advance how Defendants will try to kill him, and therefore denied a meaningful opportunity to come into court to challenge that method of execution, as protected by the Fourteenth Amendment

(6) be denied the fundamental right to Free Speech under the First Amendment, because the Execution Protocol vests in the Warden complete discretion to cut off the inmate's last words based on the Warden's subjective interpretation of those words as offensive or lengthy, but the Execution Protocol contains no standards by which to determine what is too offensive or lengthy.

828. The individual and/or pattern of deviations and/or variations from DRC Defendants' Execution Policy and written execution protocol exhibited by many of the actors involved, intentionally and/or recklessly, combined with their wholly subjective, discretionary understanding and application of the execution policy and written Execution Protocol, along with substantial evidence of incompetence or inability to

perform in the execution context cumulatively point to an unacceptable risk of violating Plaintiff's rights.

829. Defendants rely on Incident Command Systems principles to implement their Execution Protocol.

830. Defendants have applied Incident Command Systems principles at various times in their execution policy as a sword, a purported guarantee against deviations or variations from the written execution protocol.

831. And at other times Defendants have applied ICS as a shield by arguing that they need not strictly follow ICS since it is not officially incorporated into 01-COM-11.

832. But by virtue of DRC Policy 310-SEC-14, ICS principles should be incorporated formally into Defendants' administration of 01-COM-11.

833. Defendants' application of ICS principles has been inconsistent over time and, upon information and belief, is dependent on the subjective discretion of the Warden of SOCF, the Warden of CCI, and/or the Director of DRC, and the identities of the individuals who occupy those positions change regularly.

834. Moreover, the veracity of documents Defendants produce is now called into question, based on new evidence of falsification of official records and documents and/or misrepresentations following incidents including or similar in significance to administration of 01-COM-11, including the McGuire "investigation" and report.

835. Core Elements #5 of the 2013 Execution Protocol is no more than a sham. Despite seemingly mandatory, limiting language of Core Element # 5, the authority to authorize variations/deviations from the written protocol's requirements is, in fact,

unfettered, because the Execution Protocol does not limit the sole authority to authorize deviations or variations from the written protocol to just a single person.

836. Instead, by the terms of 01-COM-11, any of an unidentified number of persons, with unknown experience, qualification and the like may be considered "the Director" at any given time, injecting more discretion into the execution protocol.

837. The redefinition of "the Warden" in the 2013 Execution Protocol multiplies that problem.

838. DRC Defendants claim that only a single person other than the DRC Director—that is, Defendant Voorhies—would ever be designated as the Director's designee.

839. But Defendants, given the chance to include that critical limit on discretion in recent amendments of their Execution Protocol, declined to formalize that purported restriction.

840. Defendants' assurance that one, and only one, other person would ever be designated as the Director's designee bear no indicia of reliability when that which DRC Defendants have previously sworn is later discarded when inconvenient.

841. Defendants' actions in aggressively seeking legislation to keep secret a great deal of information related to their activities related to the Execution Protocol and their application of it will permit Defendants to hide deviations from the Execution Protocol, including violations of state and federal law, rather than affording open and meaningful oversight.

842. Defendants' actions administering their Execution Policy and written execution protocol show a pattern of deviations and/or variations from the Execution Policy and/or written execution protocol, intentionally, recklessly and/or arbitrarily, such

that the safeguards allegedly contained in Defendants' Execution Policy and written execution protocol are applied to a particular inmate arbitrarily and disparately, and that such deviations and/or variations are arbitrary and irrational, and/or not necessary to achieve a compelling governmental interest.

843. Upon information and belief, Defendants have also violated federal and/or state law governing drug manufacturing, compounding, and controlled substances through their deviations and/or variations from their execution policy and written Execution Protocol.

844. Defendants have also deviated from their Execution Protocol when they have violated or violate applicable federal and/or state statutory or regulatory laws discussed herein.

845. Defendants' actions deny Plaintiff the guarantee that he will receive the full panoply of procedural safeguards in the written Execution Protocol.

846. Thus, Defendants' pattern of deviations and/or variations from their execution policy and written Execution Protocol results in each condemned inmate being treated differently and such disparate treatment severely burdens the fundamental rights of the class of persons that includes Plaintiff.

847. Defendants' disparate treatment of Plaintiff arising from their individual and/or pattern of deviations and/or variations from their execution policy and written Execution Protocol is not necessary to achieve any compelling governmental interest, nor is it the least restrictive means to achieve any compelling governmental interests

848. Defendants' execution policy and written Execution Protocol, as applied based on Defendants' repeated pattern of deviations/variations from the execution policy and written execution protocol, violate the Equal Protection Clause of the Fourteenth

Amendment because they burden the fundamental rights of the group of condemned inmates—which includes Plaintiff—as articulated in ¶ 827 above and in the various causes of action articulated herein, without being necessary to achieve a compelling governmental interest.

849. Defendants' execution policy and written Execution Protocol facially violates the Equal Protection Clause because they codify unequal treatment of similarly situated individuals in such a way that it burdens the fundamental rights of the group of condemned inmates—which includes Plaintiff—as articulated in ¶ 827 above and in the various causes of action articulated herein, without being necessary to achieve a compelling governmental interest.

2. Equal Protection violation based on burdening of Plaintiff's fundamental rights by Defendants' deviations from Ohio's execution statute.

850. Plaintiff is similarly situated to other condemned inmates to whom Defendants will apply Ohio's execution statute, Ohio Revised Code § 2949.22.

851. Ohio Revised Code § 2949.22(A) requires that "a death sentence shall be executed by causing the application to the person, upon whom the sentence was imposed, of a lethal injection of a drug or combination of drugs of sufficient dosage to quickly and painlessly cause death. The application of the drug or combination of drugs shall be continued until the person is dead."

852. Defendants will apply § 2949.22 to Plaintiff disparately, in violation of the Equal Protection Clause's guarantee of equal protection of the laws.

853. Defendants will intentionally and/or recklessly deviate from § 2949.22, and therefore apply the law disparately without compelling governmental interest, by failing to ensure that Plaintiff's execution will be quick.

854. Defendants will intentionally and/or recklessly deviate from § 2949.22, and therefore apply the law disparately without a compelling governmental interest, by failing to ensure that Plaintiff's execution will be painless.

855. Defendants will intentionally and/or recklessly deviate from § 2949.22, and therefore apply the law disparately without a compelling governmental interest, by failing to continue application of the lethal-injection drug until Plaintiff is dead.

856. Defendants will intentionally and/or recklessly deviate from § 2949.22, and therefore apply the law disparately without a compelling governmental interest, by failing to administer a sufficient dosage of the lethal-injection drug.

857. Defendants' deviations from § 2949.22's non-discretionary mandates substantially burden the fundamental rights of the class of persons that includes Plaintiff by increasing the risks identified in ¶ 827 above and in the various causes of action articulated herein, without being necessary to achieve a compelling state interest.

3. Equal Protection violation based on burdening of Plaintiff's fundamental rights by Defendants' deviations from Ohio's constitution.

858. Plaintiff is similarly situated to other condemned inmates against whom Defendants will apply Ohio's execution statute, Ohio Revised Code § 2949.22 and the Execution Protocol, under Ohio's state Constitution, Section 9, Article I, which prohibits inflicting "cruel and unusual punishments."

859. Section 9, Article I of the Ohio Constitution is not limited to the reach of the federal constitution's Eighth Amendment Cruel and Unusual Punishments Clause, because Ohio's Constitution may accord greater civil liberties and protections to individuals and groups than its federal counterpart.

860. Defendants will apply Section 9, Article I of the Ohio Constitution to Plaintiff disparately, in violation of the Equal Protection Clause's guarantee of equal protection of the laws.

861. Defendants will intentionally and/or recklessly deviate from the "cruel and unusual punishments" clause of Section 9, Article I of the Ohio Constitution, and therefore apply the law disparately without a compelling governmental interest, by failing to ensure that Plaintiff's execution will not be a cruel and unusual punishment under the state constitution's greater civil liberties and protections than the federal Eighth Amendment.

862. Defendants' deviations from the "cruel and unusual punishments" clause of Section 9, Article I of the Ohio Constitution substantially burden the fundamental rights of the class of persons that includes Plaintiff by increasing the risks identified in ¶ 827 above and in the various causes of action articulated herein, without being necessary to achieve a compelling state interest.

4. Equal Protection violation based on burdening of Plaintiff's fundamental rights by Defendants' failing to follow federal and Ohio state laws related to imported drugs, unapproved drugs, misbranded drugs, adulterated drugs, controlled substances, or compounded drugs, including compounding sterile injectable controlled substances to be used as execution drugs.

863. Plaintiff is similarly situated to others in the general population of persons subject to the federal and Ohio state drug laws identified herein, and/or those persons intended to be protected by those laws, and/or others in DRC Defendants' custody to whom drugs will be administered.

864. In their violations of federal and Ohio state laws as alleged herein, Defendants intentionally and/or recklessly treat the class of persons who are the intended

beneficiaries of those laws—which includes Plaintiff—disparately from others similarly situated, namely the general population of persons subject to those laws and/or those persons intended to be protected by those laws, and/or others in DRC Defendants' custody to whom drugs will be administered.

865. Defendants' intentional and/or reckless violations of the federal and state drug laws as alleged herein, by dramatically reducing the protections to Plaintiff's health from the possibility of harmful, dangerous, painful, adulterated, misbranded, or poorly compounded drugs, including controlled substances, that those laws were created to provide, substantially burden the fundamental rights of the group of persons that includes Plaintiff which are identified in ¶ 827 above and in the various causes of action articulated herein, without being necessary to achieve a compelling state interest.

866. Defendants' violations of the federal and state drug laws as alleged herein also intentionally and/or recklessly apply the law unequally to Plaintiff by purporting to permit Drug Source Defendants and DRC Defendants to engage in illegal activity to compound, import, dispense, distribute, administer, or otherwise engage in a broad host of activities identified herein related to controlled substances to be used as execution drugs, when such activity would ordinarily subject those Defendants to criminal prosecution in federal and/or state court or civil administrative enforcement sanctions for their actions.

867. Defendants' tacit endorsement of illegal activity in the name of carrying out an execution at all costs is arbitrary and irrational, and especially when combined with Defendants' strong desire to keep secret their activities related to executions, it

substantially burdens the fundamental rights of the group of persons that includes Plaintiff which are identified in ¶ 827 above and in the various causes of action articulated herein—especially Plaintiff's Due Process Clause right to be free from governmental activity that shocks the conscience, his Eighth Amendment right to be free from a substantial risk of serious harm, and his rights against being an unwilling, non-consenting subject of human experimentation—without being necessary to achieve a compelling state interest.

5. Equal Protection violation based on burdening of Plaintiff's fundamental rights by Defendants' deviations from Ohio's definition-of-death law.

868. Plaintiff is similarly situated to others to whom Ohio's definition-of-death law, Ohio Revised Code § 2108.40, applies.

869. DRC Defendants intentionally and/or recklessly apply Ohio statutory law disparately to Plaintiff when they deviate from the statute that defines, for purposes of Ohio law, when death has occurred, by declaring Plaintiff's death following injection of the lethal drugs under the Execution Protocol within the time when the cessation of circulatory and respiratory functions or all functions of the brain, including the brain stem, remains reversible with the appropriate resuscitative care.

870. By using an Execution Protocol that they know will produce a lingering death of indeterminate duration, Defendants are intentionally and/or recklessly treating Plaintiff and other condemned inmates disparately.

871. Instead of applying the statute, DRC Defendants and their agents will determine death prematurely at a time to be determined at Defendants' discretion, and then proceed as if Defendant is dead when he will not be.

872. DRC Defendants' disparate application of Ohio's definition-of-death statute substantially burdens the fundamental rights of the group of persons that includes Plaintiff which are identified in ¶ 827 above and in the various causes of action articulated herein, without being necessary to achieve a compelling state interest.

6. Equal Protection violation based on burdening of Plaintiff's fundamental rights by Defendants' deviations from federal and Ohio state laws prohibiting non-consenting human experimentation.

873. Plaintiff is similarly situated to others to whom federal and Ohio state laws prohibiting non-consenting human experimentation are applicable, including those who have a fundamental right against being the non-consenting, unwilling subject of human experimentation by virtue of being United States citizens, those who are protected by ODRC Policy 68-MED-11, Protocol Numbers E-1 through E-4 and ODRC Policy 06-RES-02, by virtue of being in ODRC's custody, and those who are protected by the federal and state statutes and regulations related to new drugs, approved or unapproved drugs, or the Investigational New Drug Application requirements.

874. Defendants intentionally and/or recklessly deviate from the federal and Ohio state laws identified herein by engaging in human experimentation on Plaintiff, an unwilling, non-consenting experimental subject, through experimenting with untested and unknown methods of execution in the Execution Protocol, and Defendants' manufacturing, compounding, dispensing, administration, or other related actions of drugs that are not approved drugs.

875. Defendants intentionally and/or recklessly deviate from the federal and Ohio state laws by engaging in human experimentation on Plaintiff, an unwilling, non-consenting experimental subject, through application of the Execution Protocol and

Defendants' manufacturing, compounding, dispensing, administration, or other related actions of drugs that will be manufactured, compounded, shipped, stored, and other things without meaningful oversight by Defendants who are ethically compromised and who have been promised a cloak of anonymity and lack of repercussions for their actions.

876. Especially given the statutory efforts to cloak execution matters in secrecy that Defendants aggressively advocated and sought, there is no assurance that the drugs to be used for an execution will be the same from execution to execution, making each execution an experiment on an non-consenting, unwilling human subject.

877. Defendants' disparate application of federal and Ohio state laws prohibiting administering drugs to an unwilling, non-consenting human subject Ohio's definition-of-death statute substantially burdens the fundamental rights of the group of persons that includes Plaintiff which are identified in ¶ 827 above and in the various causes of action articulated herein—especially the fundamental right against being an unwilling, non-consenting human experimentation subject protected by the Fourteenth Amendment's Due Process Clause, the Ninth Amendment, and the Privileges or Immunities Clause of the Fourteenth Amendment—without being necessary to achieve a compelling state interest.

7. Equal Protection violation based on burdening of Plaintiff's fundamental rights by Defendants' use of an Execution Protocol and policies by which Defendants deny necessary medical and resuscitative care and permit a lingering death.

878. Plaintiff is similarly situated to others in ODRC's custody for whom the State of Ohio, through ODRC and its employees and agents, are responsible under the Eighth Amendment to provide necessary medical care.

879. Defendants are intentionally and/or recklessly treating Plaintiff and other condemned inmates disparately as compared to other Ohio inmates in DRC Defendants' custody by failing to provide the necessary medical and resuscitative care to Plaintiff after his sentence has been imposed by virtue of Defendant Warden declaring him dead, but before he is dead in accordance with Ohio law, Ohio Revised Code § 2108.40.

880. At the point Defendant Warden declares the condemned inmate dead, the death warrant has been satisfied, but the inmate will still be statutorily and medically alive, and therefore entitled to necessary medical and resuscitative care that Defendants intentionally and/or recklessly deny.

881. Defendants know or should know that human executions using compounded execution drugs have consistently taken significantly longer than executions using domestically manufactured drugs.

882. By using an Execution Protocol that they know will produce a lingering death of indeterminate duration and then refusing to provide necessary medical and resuscitative care after they declared death but before Plaintiff is legally and medically dead, Defendants are intentionally and/or recklessly treating Plaintiff and other condemned inmates disparately.

883. Defendants' disparate application of necessary medical and resuscitative care to Plaintiff substantially burdens the fundamental rights of the group of persons that includes Plaintiff which are identified in ¶ 827 above and in the various causes of action articulated herein—especially the fundamental right to receive necessary medical care guaranteed by the Eighth Amendment—without being necessary to achieve a compelling state interest.

B. Equal Protection—Class of One

884. To succeed on a "class-of-one" equal protection claim, a plaintiff must allege either disparate treatment from similarly situated individuals and that the government actors had no rational basis for the difference, *Assocs. of Cleveland Fire Fighters v. City of Cleveland, Ohio*, 502 F.3d 545, 549 (6th Cir. 2007), or that the 'challenged government action was motivated by animus or ill-will,' EJS Properties, LLC v. City of Toledo, 698 F.3d 845, 864 (6th Cir. 2012)." *Paterek v. Vill. of Armada*, No. 14-1894, 2015 U.S. App. LEXIS 15932, *43 (6th Cir. Sept. 8, 2015).

885. Defendants intentionally treat Plaintiff differently than similarly situated individuals by their deviations from or failure to follow the relevant law in a manner that is detrimental to Plaintiff by increasing the risk of a burden on his various fundamental rights identified herein.

886. Defendants' disparate treatment of Plaintiff is so unrelated to achievement of any combination of legitimate purposes that it must be irrational and arbitrary.

887. Trying to carry out an execution under any procedure that might accomplish the task is not a sufficient basis to rationally justify Defendants' disparate treatment of Plaintiff.

888. Defendants' actions are pure arbitrariness—they are irrational and arbitrary by definition because they are in contravention of the law, which negatives any conceivable basis that might support Defendants' actions.

1. Equal Protection violation based on Defendants' unequal application of the Execution Protocol to Plaintiff as a class of one.

889. Plaintiff is a "class of one," similarly situated with any other condemned inmate who has been or will be subjected to Defendants' execution policy and written Execution Protocol.

890. Plaintiff has been or will be singled out arbitrarily and irrationally as a "class of one" who will not be afforded equal protection as represented by the procedural safeguards in Defendants' written Execution Protocol, when such written safeguards are disregarded, ignored, deemed discretionary or advisory only, or otherwise not followed, intentionally and/or otherwise, during administration of the overarching execution policy.

891. Plaintiff has been or will be treated differently from other similarly situated individuals without any rational basis for the difference in treatment as a class of one, irrationally and arbitrarily, in violation of the guarantees of the Equal Protection Clause of the Fourteenth Amendment.

892. Defendants' individual and/or pattern of deviations and/or variations from their execution policy and written execution protocol arbitrarily and irrationally treat Plaintiff differently from similarly situated inmates.

893. Defendants have demonstrated a pattern of irrationally and arbitrarily deviating and/or varying from their execution policy and written execution protocol without any legitimate governmental interest. Combined with the nearly limitless discretion vested in certain actors in the execution process, this means that Plaintiff's death sentence will be administered in a manner such that he will be arbitrarily and irrationally treated differently than similarly situated individuals, to his detriment in

the form of increased risk of violations of his fundamental rights, therefore violating his rights as a class of one under the Fourteenth Amendment's Equal Protection Clause.

894. Defendants' disparate treatment of Plaintiff arising from their individual and/or pattern of deviations and/or variations from their execution policy and written execution protocol is arbitrary, irrational, and furthers no legitimate state interests, and/or there is no relationship between the deviations and/or variations and any legitimate state interest

895. Defendants' pattern of deviations and/or variations is irrational because it is arbitrary and capricious; it is a pattern of random deviations and/or variations that changes from execution to execution.

896. Defendants' arbitrary application of their Execution Protocol is all the more detrimental to Plaintiff because open oversight and scrutiny by Plaintiff and other inmates, this Court, and the public have been key in exposing significant constitutional violations regarding Defendants' execution processes and protocols.

897. But after Defendants sought, and Defendant Kasich signed, legislation creating Ohio Revised Code § 2949.221-222, there will be virtually no oversight of any actions related to carrying out the Execution Protocol, and Defendants subjectively believe that there will be virtually no oversight of their actions.

898. Reducing the level of protection against the risk of harms caused by the Execution Protocol is arbitrary and irrational.

899. Any justifications that Defendants have offered for their deviations and/or variations from the Execution Protocol are without any rational relationship to a particular condemned inmate.

900. Defendants' justifications for their deviations and/or variations amount to claims of administrative convenience, which is not a legitimate governmental interest.

901. By arbitrarily and/or inconsistently following, deviating or varying from the procedural safeguards in Defendant's execution policy and written Execution Protocol, and without any justification related to any specific condemned inmate or to any compelling or legitimate governmental interest, Defendants are arbitrarily denying or significantly burdening Plaintiff's fundamental rights as articulated in ¶ 827 above and in the various causes of action articulated herein.

902. Defendants' execution policy and written execution protocol are considered binding state law, and thus Defendants violate state law when they fail to abide by the explicit mandates of their execution policy and/or written execution protocol.

903. Upon information and belief, Defendants have also violated federal and/or state law governing drug manufacturing, compounding, and controlled substances through their deviations and/or variations from their execution policy and written execution protocol.

904. Even if otherwise strictly abiding by their execution policy and written Execution Protocol, Defendants have still violated federal and state law governing drug manufacturing, compounding, and controlled substances in a way that disparately applies the law to Plaintiff as a class of one, irrationally.

905. Defendants have arbitrarily and irrationally deviated from their Execution Protocol, including from Core Elements of the Execution Protocol from which deviations are allegedly impermissible, when they have violated or violate applicable federal and/or state statutory or regulatory laws discussed herein, to Plaintiff's detriment.

906. State actions that are clearly contrary to law are irrational, and therefore Defendants' deviations and/or variations from, and disregard and violations of, binding law in the form of the Execution Protocol and other applicable federal and state statutes and regulations, are irrational.

907. Condemned inmates subject to Defendants' execution policy and their written execution protocol—including Plaintiff—are dissimilar only in immaterial respects as it relates to Defendants' pattern of deviations and/or variations, and/or Defendants' deviations and/or variations are not rationally founded on differences that are real and not illusory.

908. By arbitrarily and/or inconsistently following, deviating or varying from the procedural safeguards in Defendants' execution policy and written execution protocol, Defendants are arbitrarily and intentionally treating Plaintiff differently than other similarly situated inmates or irrationally singling him out as a class of one without any relation to differences between Plaintiff and otherwise-similarly-situated individuals, to Plaintiff's detriment and contrary to law or otherwise without any rational relationship to a legitimate governmental interest.

909. Defendants' execution policy and written execution protocol facially violates Plaintiff's rights as a class of one under the Equal Protection Clause because they codify arbitrary and irrational unequal treatment of similarly situated individuals,

such as Plaintiff, without any legitimate governmental interest and in a detrimental manner to Plaintiff, and Defendants seek to hide this arbitrary and irrational unequal treatment from Plaintiffs, the media, the courts, or the general public.

2. Equal Protection violation based on Defendants' unequal application of Ohio's execution statute to Plaintiff as a class of one.

910. Plaintiff is a "class of one," similarly situated with any other condemned inmate who has been or will be subjected to Ohio's execution statute, § 2949.22.

911. Defendants' implementation of Ohio Rev. Code § 2949.22 and the Execution Protocol irrationally, intentionally and/or recklessly treats death-row inmates, including Plaintiff, disparately by arbitrarily subjecting inmates to painful, lingering, undignified, spectacle executions despite its obligation to consistently provide quick and painless executions.

3. Equal Protection violation based on Defendants' unequal application to Plaintiff, as a class of one, of federal and Ohio state laws related to imported drugs, unapproved drugs, misbranded drugs, adulterated drugs, controlled substances, or compounded drugs, including compounding sterile injectable controlled substances to be used as execution drugs.

912. Plaintiff is a "class of one," similarly situated with those who are subject to those laws or those who are intended to be protected and kept safe from exposure to harmful drug products by those laws—specifically, those persons who will be exposed to controlled substances, or drug products produced by manufacturers, foreign or domestic, or by compounding pharmacies or outsourcing facilities.

913. Defendants intentionally and/or recklessly treat Plaintiff as a class of one disparately from others similarly situated.

914. Defendants' intentional and/or reckless violations of the federal and state drug laws intentionally violate Plaintiff's rights as a class of one, arbitrarily and irrationally,

thereby exposing him to significant risks of harm from illegal and illegally sourced drugs and significantly burdening his fundamental rights as identified herein, without any rational relationship to any legitimate state interest, because state actions that are clearly contrary to law are irrational.

915. Any possible rational or legitimate state interest is "negatived" when Defendants' actions are in violation of the law and are, therefore, arbitrary and capricious by definition.

916. Defendants' intentional and/or reckless violations of the federal and state drug laws as alleged herein, by dramatically reducing the protections to Plaintiff's health from the possibility of harmful, dangerous, painful, adulterated, misbranded, or poorly compounded drugs, including controlled substances, that those laws were created to provide, arbitrarily and irrationally expose Plaintiff, to his detriment, to the risks identified in ¶ 827 above and in the various causes of action articulated herein, without any rational relationship to a legitimate state interest.

917. That level of risk to Plaintiff is increased significantly due to the restrictions on oversight in Ohio Revised Code § 2949.221-222 that were recently created at Defendants' behest and signed into law by Defendant Kasich.

918. Defendants' violations of the federal and state drug laws as alleged herein also intentionally and/or recklessly apply the law unequally to Plaintiff by purporting to permit Drug Source Defendants and DRC Defendants to engage in illegal activity to compound, import, dispense, distribute, administer, or otherwise engage in a broad host of activities identified herein related to controlled substances to be used as execution drugs, when such activity would ordinarily subject those Defendants to

criminal prosecution in federal and/or state court or civil administrative enforcement sanctions for their actions.

919. Defendants' tacit endorsement of illegal activity in the name of carrying out an execution at all costs is arbitrary and irrational, and especially when combined with Defendants' strong desire to keep secret their activities related to executions, Plaintiff is detrimentally affected by Defendants' lawless activities, including by substantially burdening his fundamental rights identified in ¶ 827 above and in the various causes of action articulated herein.

4. Equal Protection violation based on Defendants' unequal application of Ohio's definition-of-death law to Plaintiff as a class of one.

920. Plaintiff is a "class of one," similarly situated to others to whom Ohio's definition-of-death law, Ohio Revised Code § 2108.40, applies.

921. DRC Defendants will intentionally and/or recklessly apply Ohio's definition-of-death law to him disparately if they apply it to him at all, to his detriment and irrationally because he will likely still be alive, statutorily and medically, at the time DRC Defendants declare him dead and proceed with steps in the Execution Protocol such as removing him from the execution chamber and loading him into the vehicle to deliver him to the person who is responsible for taking possession of Plaintiff's remains.

922. The range of times in which DRC Defendants declare death suggests an arbitrary and/or irrational application, if at all, of Ohio's definition-of-death law.

5. Equal Protection violation based on Defendants' unequal application of federal and Ohio state laws prohibiting non-consenting human experimentation to Plaintiff as a class of one.

923. Plaintiff is a "class of one," similarly situated with those who are protected by from federal and state laws prohibiting human experimentation on non-consenting, unwilling human subjects.

924. DRC Defendants will intentionally and/or recklessly treat Plaintiff disparately by subjecting him to human experimentation to which Plaintiff has not and does not consent, as alleged herein, to Plaintiff's detriment.

925. DRC Defendants' disparate treatment is arbitrary and irrational because it violates applicable federal and state-law prohibitions on non-consenting human experimentation, as alleged herein.

6. Equal Protection violation based on Defendants' disparate denial of necessary medical care and permitting a lingering death.

926. Plaintiff is a "class of one," similarly situated to others in ODRC's custody for whom the State of Ohio, through ODRC and its employees and agents, are responsible under the Eighth Amendment to provide necessary medical care.

927. Plaintiff is a "class of one," similarly situated to others to whom DRC Defendants will administer its Execution Protocol using compounded execution drugs and thereby produce a lingering death.

928. DRC Defendants will treat him disparately, intentionally and/or recklessly, by failing to provide the necessary medical care and permitting a lingering death instead.

929. DRC Defendants' actions are arbitrary and irrational, as DRC Defendants have a duty under the Eighth Amendment to provide necessary medical care to one in their custody, and to prevent subjecting Plaintiff to a lingering death.

Fifth Cause of Action: Violations of Fundamental Rights Arising Under The Principles Of Liberty and/or Natural Law Which Are Protected By The Ninth Amendment.

930. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

931. Defendants' application of their execution policy and written execution protocol, as demonstrated through previous executions such as Clark, Newton, Biros, Berry, McGuire, and the failed execution of Broom, and as alleged above, along with the facts alleged above related to executions of inmates in other states using execution protocols similar or identical to Defendants' protocol and procedures and Defendants' connection to those executions, will violate Plaintiff's fundamental, unenumerated rights arising under the principles of liberty and/or natural law that are protected by the Ninth Amendment.

932. These rights include rights such as Plaintiff's right to privacy, his right to personal dignity, his right to bodily integrity, his right to not be the unwilling subject of forced, involuntary human experimentation conducted by Defendants, and others inherent in the concepts of liberty and/or natural law.

933. These fundamental rights, arising from the concepts of liberty and natural law that guided the Framers' understanding of the Ninth Amendment specifically and the Bill of Rights in general, are deeply rooted in this Nation's history and tradition, and they are implicit in the concept of ordered liberty.

934. Defendants will violate Plaintiff's fundamental, unenumerated rights in violation of the Ninth Amendment through Defendants' haphazard and faulty administration of their execution policy and written execution protocol, including, but not limited to,

Defendants' demonstrated inability to consistently obtain IV access quickly and with a minimum number of needle sticks, Defendants' inconsistent application of ICS principles over time, Defendants' demonstrated willingness to discount evidence of significant problems during an execution, Defendants' demonstrated unwillingness to recognize the need for resuscitative medical care and equipment on hand and the corresponding need to accurately assess when an inmate has legally died, and Defendants' insistence to this Court that they have not and will not illegally obtain execution drugs even after evidence is revealed suggesting that they have tried to obtain execution drugs in violation of the law.

935. Defendants will violate Plaintiff's fundamental, unenumerated rights in violation of the Ninth Amendment through their administration of execution drugs, compounded or otherwise, that will cause vomiting, choking, asphyxiating, suffocating, gasping, seizing, tremors, a heart attack, and other disturbing reactions, resulting in an undignified, spectacle execution, or attempted execution, offensive to an inmate's rights protected by the Ninth Amendment.

936. Defendants will violate Plaintiff's fundamental, unenumerated rights in violation of the Ninth Amendment through their application of their execution policy's and written execution protocol's various tasks in such a way as to result in an undignified, spectacle execution, or attempted execution, offensive to an inmate's rights protected by the Ninth Amendment.

937. Forcing an non-consenting prisoner to be the unwilling, involuntary subject of pharmaceutical or medical experimentation performed on him by those who hold him in custody has long been prohibited internationally, by the United States in

accordance with binding international treaties and under controlling federal drug statutes and regulations, and is even prohibited by DRC Defendants' own departmental policies. *See* ODRC Policy 68-MED-11, Protocol Number E-4, Pharmacy Distribution and Dispensing Operations, ¶ III.D, Experimental or Investigational Drugs; ODRC Policy 06-RES-02, Human Subjects Research Policy, ¶ VI.A.5.c (stating that investigational or experimental projects "that represent a risk to offenders are not allowed"); ¶ VI.A.5.d (experiments involving offenders as human subjects which will be conducted by those under DRC's jurisdiction not permitted); ¶ VI.C.1 (stating the "participation of offenders under the jurisdiction of the Department in medical, pharmaceutical, and/or cosmetic projects is prohibited unless there is clear benefit to the individual offender based on his/her need for a specific medical procedure or pharmaceutical that is not generally available. **Participation of offenders** in medical or **pharmaceutical testing purely for experimental** or research purposes **is not permitted**.") (emphasis added).

938. Defendants will violate Plaintiff's fundamental, unenumerated rights in violation of the Ninth Amendment through their application to him of experimental or investigational drugs, to which he does not and, indeed cannot, consent, thereby forcing him to become the unwilling, involuntary subject of forced human experimentation in violation of an inmate's rights protected by the Ninth Amendment.

939. In all the foregoing ways, Defendants violate Plaintiff's fundamental, unenumerated rights in violation of the Ninth Amendment to the United States Constitution and 42 U.S.C. § 1983.

Sixth Cause of Action: First Amendment Free Speech Clause Violations

940. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

941. Defendants' written protocol places restrictions on the length and content of an inmate's last statement, and those restrictions are not necessary or the least restrictive means to achieve a governmental interest.

942. The restrictions will have a chilling effect on an inmate's expressive speech because the written protocol gives the Warden discretionary but unguided authority to impose restrictions on the length of an inmate's last statement, and to terminate a statement based on content, *i.e.*, to terminate a statement if the Warden subjectively believes it is intentionally offensive to others, without any further explanation on how those restrictions are to be applied.

943. Plaintiff has a fundamental right protected by the First Amendment, the Ninth Amendment, and the Fourteenth Amendment to the federal constitution to make a final statement free of the restrictions contained in Defendants' written protocol.

944. The restrictions in Defendants' written protocol related to an inmate's last words violate well-established First Amendment prohibitions on content-based discrimination in regulating speech.

945. The restrictions in Defendants' written protocol related to an inmate's last words violate well-established First Amendment prohibitions related to the public forum and/or limited public forum doctrines.

946. The restrictions in the written protocol related to an inmate's last words discriminate against an inmate's expressive speech on the basis of viewpoint, because the Warden

may impose restrictions the Warden subjectively believes to be intentionally offensive.

947. The restrictions in the written protocol related to an inmate's last words are not reasonable in light of the purpose of an execution, and Plaintiff is provided no alternative way to communicate the entirety of his last words if the Warden restricts Plaintiff's speech.

948. There are no governmental interests to justify the restrictions on an inmate's expressive speech provided in the written protocol.

949. The written protocol, facially and as applied to him, violates Plaintiff's freedom of speech rights protected by the First, Ninth and Fourteenth Amendments.

950. Upon information and belief, the restrictions in Defendants' written protocol related to an inmate's last words also violate the terms of a settlement agreement to which some of the original Defendants in these lethal injection cases, and at least one former Plaintiff in this action, Frederick Treesh, were a party, in *Treesh v. Taft*, No. 99-624, S.D. Ohio.

951. Upon information and belief, under the terms of the settlement agreement, Defendants' protocol would place no restrictions on the content and/or the duration of an inmate's last statement.

952. In all the foregoing ways, Defendants violate Plaintiff's rights to free speech protected by the First Amendment to the United States Constitution and 42 U.S.C. § 1983.

Seventh Cause of Action: Fourteenth Amendment Due Process Violation

953. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

954. DRC Defendants have failed to inform Plaintiff about which method of execution they intend to apply to him, reserving for themselves the option of using Plan 1 or Plan 2.

955. DRC Defendants have not provided Plaintiff with the identification information of any of the Drug Source Defendants from whom they will obtain the execution drugs to be used at the Plaintiff's execution.

956. Indeed, DRC Defendants were actively involved, in late 2014, in efforts to persuade the Ohio General Assembly to introduce and enact legislation, *i.e.*, HB 663, that would cause the identification information of Drug Source Defendants and others to be: (a) classified as confidential, privileged under law, and not subject to disclosure by any person, state agency, governmental entity, board, or commission or any political subdivision as a public record under section 149.43 of the Ohio Revised Code or otherwise; (b) no longer subject to disclosure by or during any judicial proceeding, inquiry, or process, except as otherwise provided in the new law; and (c) no longer subject to discovery, subpoena, or any other means of legal compulsion for disclosure to any person or entity, except as otherwise provided in the new law.

957. These efforts resulted in the enactment of HB 663, which became effective March 23, 2015, and the pertinent provisions referenced here are codified at Ohio Revised Code §§ 149.43(A)(1)(cc), 2949.221, and 2949.222.

958. Under the purported authority of the referenced provisions of HB 663, DRC Defendants have refused to provide Plaintiff with the identification information of any of the Drug Source Defendants from whom DRC Defendants will obtain the execution drugs to be used at the Plaintiff's execution.

959. "The fundamental requisite of due process of law is the opportunity to be heard. This right to be heard has little reality or worth unless one is informed that the matter is pending . . . ." *Mullane v. Cent. Hanover Bank & Trust Co.*, 339 U.S. 306, 314 (1950) (internal citations omitted).

960. "Fundamental fairness, if not due process, requires that the execution protocol that will regulate a prisoner's death be forwarded to him in prompt and timely fashion." *Oken v. Sizer*, 321 F. Supp. 2d 658, 664 (D. Md. 2004), *stay vacated*, 542 U.S. 916 (2004).

961. The Execution Protocol purports to provide timely notice to an inmate of the manner in which he or she will be executed including the execution drugs to be used, but that assurance is merely illusory.

962. There is no definitive deadline in the written protocol by which the Warden must inform the inmate of what the Warden has decided, and the Medical Team can make a different determination at any time—including even the morning of a scheduled execution—without any further notice to the inmate required.

963. DRC Defendants fail and refuse to provide critically relevant information concerning the identification information of the Drug Source Defendants and their experience, training, qualifications, credentials, and performance history.

964. By failing to require and provide adequate notice of exactly which method of execution the Defendants will use, and of the identification information of the Drug Source Defendants, Defendants are depriving Plaintiff of his right to notice and an opportunity to be heard, in violation of the Due Process Clause of the Fourteenth Amendment.

965. Furthermore, because there is no requirement for background checks, credentialing, or anything of the sort related to which Drug Source Defendants with whom the DRC Defendants will work to manufacture execution drug(s), or Drug Source Defendants' drug manufacturing facilities, and because there is no mechanism by which any assessments or quality-control inspections, testing, analysis, or other similar procedures of any kind are done to ensure strict compliance with all relevant federal and State of Ohio laws and Core Elements ## 1, 2, and 3, Defendants are depriving Plaintiff of his right to notice and an opportunity to be heard, in violation of the Due Process Clause of the Fourteenth Amendment.

966. Plaintiff will have no meaningful opportunity to challenge the involvement of Drug Source Defendants in a critical aspect of the written execution protocol if he is not informed in advance about the source of the execution drug(s) to be used for his execution, the specific involvement of each and every Drug Source Defendant, and the identification information of such Drug Source Defendants.

967. Nor will he have a meaningful opportunity to challenge the use of execution drugs manufactured for the sole purpose of killing him which have a substantial, objectively intolerable risk of being something other than the pure, sterile, unadulterated, not-expired/not past their use-by date, not-imported drugs of the proper concentration,

potency, content, pH level and other relevant characteristics, as required to be used by the 2015 Execution Protocol and Defendants' execution policies.

968. In all the foregoing ways, Defendants violate Plaintiff's rights to due process protected by the Fourteenth Amendment to the United States Constitution and 42 U.S.C. § 1983.

Eighth Cause of Action: Fourteenth Amendment Due Process Clause Violations For Experimenting On Non-Consenting Prisoners

969. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

970. The Fourteenth Amendment protects the liberty and privacy right one has in the integrity of one's body. *See Rochin v. California*, 342 U.S. 165, 169 (1952); *Hurtado v. People of California*, 110 U.S. 516, 536 (1884).

971. "[N]eedlessly severe intrusions of an individual's body, *even if that individual [i]s a felon and stripped of most of his liberty*, [are] impermissible under the Due Process Clause of the Constitution." *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 818 (S.D. Ohio 1995).

972. Within the basic protections of individual liberty encapsulated in the Fourteenth Amendment are also the principles established in the Nuremberg Code. *Id.* at 819-22.

973. The Nuremberg Code, developed to create universal standards for carrying out human experimentation, explicitly states that "[t]he voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice . . . ." *United States of America v. Brandt* (the Medical Case), II Trials of War

Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, at 181 (1949).

974. Ohio state administrative law prohibits administration of experimental or investigational drugs to an inmate unless that drug is the only option to treat a medical condition and written approval has been obtained from the DRC Bureau of Medical Services State Medical Director and the DRC Human Subjects Review Committee. *See* ODRC Policy 68-MED-11, Protocol Number E-4, Pharmacy Distribution and Dispensing Operations, ¶ III.D, Experimental or Investigational Drugs.

975. Ohio state administrative law also prohibits participation of offenders in medical or pharmaceutical testing purely for experimental purposes. ODRC Policy 06-RES-02, Human Subjects Research Policy, ¶ VI.C.1.

976. Ohio state administrative law also prohibits investigational or experimental projects "that represent a risk to offenders." *Id.* at ¶ VI.A.5.c.

977. Ohio state administrative law also prohibits experiments involving offenders as human subjects which will be conducted by those under DRC's jurisdiction, such as DRC Defendants. *Id.* at ¶ VI.A.5.d.

978. Upon information and belief, no written approval to administer experimental or investigational drugs to an inmate in the context of an execution has ever been sought or obtained from the DRC Bureau of Medical Services State Medical Director and the DRC Human Subjects Review Committee.

979. The written application for approval to use experimental or investigational drugs must include the justification for use of the drug(s), as well as an informed consent statement signed by the inmate.

980. Plaintiff has not signed an informed consent statement authorizing Defendants to use investigational or experimental drug(s) on him during a lethal-injection execution, nor is carrying out his death sentence reasonably considered a "medical condition" for which use of experimental or investigational drug(s) might be permissibly considered.

981. Because of the lack of data, studies, physician expertise, and the variability of human response, every lethal injection that Defendants conduct is a human experiment. *See In re: Ohio Execution Protocol Litig.*, 994 F. Supp. 2d 906, 913 (S.D. Ohio Jan. 13, 2014).

982. The timing of scheduled executions in Ohio, when compared with the use-by date mandated under Ohio law for compounded sterile injectables, means that Defendants—if they will not be using expired drugs/drugs past their use-by date—will typically need to obtain a new order of compounded execution drugs before each execution.

983. Each execution conducted with a new batch of compounded execution drugs will be an experimental execution, because there is no guarantee that the drugs involved will be identical from execution to execution.

984. Any compounded execution drugs are also unapproved investigational New Drugs prohibited by the federal FDCA and Ohio state law, and thus experimental by definition.

985. Any imported execution drugs unapproved investigational New Drugs prohibited by the federal FDCA and Ohio state law, and thus experimental by definition.

986. The experimental nature of each execution that Defendants conduct is amplified exponentially due to the element of variability added by use of compounded execution drugs, and amplified even further because those compounded execution drugs are made by pharmacists or other Drug Source Defendants who are, by definition, ethically compromised by virtue of being willing to violate their professional ethical standards to provide drugs to be used in a human execution, and amplified further still if any of said Drug Source Defendants are permitted to remain anonymous thereby preventing Plaintiff and the Court from reasonable inquiry into and verification of the Drug Source Defendants' experience, training, qualifications, credentials, performance history, and adherence to the applicable federal and state laws.

987. Similarly, the experimental nature of each execution that Defendants conduct is amplified exponentially due to the element of variability added by use of imported and/or misbranded execution drugs, and amplified even further because those imported and/or misbranded drugs were manufactured in facilities that do not comply with U.S. manufacturing standards and exported and imported by persons who are, by definition, ethically compromised by virtue of being willing to use subterfuge and other nefarious methods to smuggle unapproved, misbranded drugs illegally into Defendants' possession, and amplified further still if any of said Drug Source Defendants are permitted to remain anonymous thereby preventing Plaintiff and the Court from reasonable inquiry into and verification of the Drug Source Defendants'

experience, training, qualifications, credentials, performance history, and adherence to the applicable federal and state laws.

988. Prisoners cannot give voluntary consent to human experimentation because they lack the free power of choice.

989. Plaintiff is a prisoner unable to exercise the free power of choice.

990. Even if he could give consent, he does not: Plaintiff does not consent to being experimented on like a human guinea pig by Defendants' use of experimental lethal injection execution drugs.

991. Defendants have no clinical basis for believing any drug combination that Defendants use to execute Plaintiff will cause death without a substantial, objectively intolerable risk of severe, unnecessary pain or suffering.

992. Defendants have no clinical basis for believing any drug combination that Defendants use to execute Plaintiff will not cause a lingering death.

993. Defendants have no clinical basis for believing any drug combination that Defendants use to execute Plaintiff will not cause a humiliating, degrading spectacle.

994. Any execution of the Plaintiff conducted by Defendants under the Execution Protocol will constitute a human experiment without voluntary consent, using unapproved investigational new drugs illegally compounded and dispensed by an ethically compromised pharmacist, or unapproved, misbranded drugs manufactured in substandard facilities and exported and illegally imported by ethically compromised Drug Source Defendants, all in violation of Fourteenth Amendment. *See In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 818 (S.D. Ohio Jan. 11, 1995).

Ninth Cause of Action: Fourteenth Amendment Privileges or Immunities Clause Violations For Experimenting on Non-Consenting Prisoners.

995. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

996. Defendants' application of their execution policy and written execution protocol, as demonstrated through previous executions such as Clark, Newton, Biros, Berry, McGuire, and the failed execution of Broom, and as alleged above, along with the facts alleged above related to executions of inmates in other states using execution protocols similar or identical to Defendants' protocol and procedures and Defendants' connection to those executions, will violate Plaintiff's fundamental, unenumerated rights protected against infringement by the Privileges or Immunities Clause of the Fourteenth Amendment.

997. These rights include rights such as Plaintiff's right to not be the unwilling subject of forced, involuntary human experimentation conducted by Defendants, which is a right secured for the citizens of the United States based on citizenship of the United States because it is a right secured by international treaties. *Slaughter-House Cases*, 83 U.S. 36, 80 (1873); *see also* McDonald v. City of Chicago, 561 U.S. 742, 851-855 (2010) (Thomas, J., concurring).

998. The right against being subject to involuntary human experimentation is clear, established as it is in numerous international treaties to which the United States is a party, including the Universal Declaration of Human Rights, G.A. Res. 217A, U.N. Doc A/810, at 71 (1947); the International Covenant on Civil and Political Rights, G.A. Res. 2200A, 21 U.N. GAOR, Supp. (No. 16) 49, 52, U.N. Doc. A/6316 (1966); the Geneva Convention, 6 U.S.T. 3316, T.I.A.S. 3364, 75 U.N.T.S. 135, Aug. 12,

1949; the Declaration on the Protection of all Persons from Being Subjected to Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, G.A. Res. 3452, Annex Art. 1 (Agenda Item 74), 30 U.N.GAOR, Supp. (No. 34) 91, U.N. Doc. A/10408 (1975); and the Nuremberg Code, G.A. Res. 161, U.N. Doc. A/PV55, at 2244 (1946).

999. Defendants' Execution Protocol constitutes a forced, involuntary human experimentation conducted by Defendants because this Court has explicitly characterized it as such: "There is absolutely no question that Ohio's current [lethal-injection] protocol presents an experiment in lethal injection processes. The science involved, the new mix of drugs employed at doses based on theory but understandably lacking actual application in studies, and the unpredictable nature of human response make today's inquiry at best a contest of probabilities." *In re Ohio Execution Protocol Litig.*, No. 2:11-cv-1016, 2014 WL 130609, at *6 (S.D. Ohio Jan. 13, 2014).

1000. Defendants' Execution Protocol also constitutes a forced, involuntary human experimentation conducted by Defendants because Defendants intend to use the administration of pentobarbital or thiopental sodium to Plaintiff to cause his death. This administration falls outside either of those drugs' marketed, FDA-approved purpose and outside the course of medical practice, and therefore constitutes the use of "New Drugs" under the FDCA. *See* 21 U.S.C. § 321(p).

1001. The FDCA "generally prohibits access to new drugs unless and until they have been approved by the Food and Drug Administration." *Abigail Alliance for Better Access*

to Developmental Drugs v. von Eschenbach, 495 F.3d 695, 697 (D.C. Cir. 2007) (en banc) (citing 21 U.S.C. § 355(a)).

1002. Before FDA approval, a new drug may only be used in humans through a clinical investigation. A "clinical investigation" is "any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice." 21 C.F.R. § 312.3(b).

1003. Defendants' Execution Protocol's experimental use of pentobarbital or thiopental sodium to kill inmates constitutes a "clinical investigation"—that is, an experiment.

1004. Plaintiff will be one of the involuntary, unwilling human "subjects" of Defendants' human experimentation as a recipient of the forcible application to him of the experimental execution drugs. 21 C.F.R. § 312.3(b).

1005. Plaintiff will also be an involuntary, non-consenting human experimentation subject under Ohio's binding administrative law. *See* ODRC Policy 68-MED-11, Protocol Number E-4, Pharmacy Distribution and Dispensing Operations, ¶ III.D, Experimental or Investigational Drugs; ODRC Policy 06-RES-02, Human Subjects Research Policy.

1006. Because Plaintiff will be an involuntary, non-consenting subject of human experimentation based on (1) this Court's characterization of Defendants' Execution Protocol; (2) the federal regulatory scheme for approving investigational or experimental new drugs; and (3) Ohio's regulatory scheme for administering experimental or investigational drugs to inmates in DRC custody, and because Plaintiff's right against being the unwilling subject of forced, involuntary human

experimentation is a fundamental right—a privilege or immunity—guaranteed to him by virtue of being a United States citizen though numerous international treaties to which the United States is a party, Defendants' application of the Execution Protocol to him will violate Plaintiff's rights protected by the Privileges or Immunities Clause of the Fourteenth Amendment even under the most restrictive reading of that clause.

Tenth Cause of Action: Ex Post Facto Violation

1007. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

1008. Defendants' Execution Protocol, as written and as applied, violates the Ex Post Facto Clause of Article 1, Sections 9 and 10 of the federal Constitution.

1009. Ohio Revised Code § 2949.22 is the provision of Ohio statutory law that establishes lethal injection as the execution method for Ohio death sentences to be carried out.

1010. Lethal injection was first added to the Ohio death penalty statute in the version of § 2949.22 that was enacted on July 2, 1993, effective October 1, 1993.

1011. In the version of § 2949.22 that was effective October 1, 1993 contained the following language:

> [T]he person's death sentence shall be executed by causing the application to the person of a lethal injection of a drug or combination of drugs of sufficient dosage *to quickly and painlessly cause death* instead of by electrocution as described in division (a) of this section. The application of the drug or combination of drugs shall be continued until the person is dead.

Ohio Rev. Code § 2949.22(B)(1) (version of statute effective Oct. 1, 1993).

1012. The next revision of § 2949.22, enacted on July 7, 1994, effective October 6, 1994, contained the same language quoted above.

1013. On November 21, 2001, the Ohio General Assembly enacted another amendment to § 2949.22, effective the same day. The November 21, 2001 version of § 2949.22 remains the effective version of the statute today.

1014. Section 2949.22(A), like the previously effective versions of Ohio's death penalty statute, requires a death sentence carried out by lethal injection to be administered by "the application to the person . . . of a lethal injection of a drug or combination of drugs of sufficient dosage *to quickly and painlessly cause death*. The application of the drug or combination of drugs shall be continued until the person is dead." Ohio Rev. Code, § 2949.22(A) (version effective Nov. 21, 2001) (emphasis added).

1015. The first written execution protocol following the addition of lethal-injection to § 2949.22 was adopted by DRC on or about March 30, 1994.

1016. The March 30, 1994 version of Ohio's lethal-injection written execution protocol stated that the purpose of the policy was "to establish a process for carrying out executions that ensures compliance with" the relevant Ohio statutory and administrative law.

1017. All subsequent versions of Ohio's written execution protocol have contained the same or substantially similar language requiring that executions must be carried out in accordance with Ohio statutory and administrative law.

1018. Plaintiff is subject to the Ohio lethal-injection statute that requires that his death by lethal-injection be carried out "quickly and painlessly."

1019. Plaintiff is and has always been subject to a written execution policy requiring adherence to Ohio statutory and administrative law.

1020. The DRC Defendants have changed the law by adopting new and greater punishment than that which first applied to Plaintiff.

1021. The current version of the written execution protocol, DRC Policy 01-COM-11, effective June 29, 2015, and previously enacted versions including those effective October 10, 2013, April 28, 2014, and January 9, 2015, diverge from the requirements for a lethal-injection execution to which Plaintiff was previously subject.

1022. These versions of 01-COM-11, as written by their inclusion of compounded execution drugs, and as applied, now fail to guarantee that Plaintiff will be executed in a manner that will "quickly and painlessly" cause his death.

1023. Evidence from executions using compounded execution drugs demonstrates that the method of execution to be imposed on Plaintiff by Defendants will not be quick, nor will it be painless, if it is carried out using compounded execution drugs.

1024. Instead, his execution will produce an agonizing, physically and mentally painful and torturous, lingering, degrading spectacle that will not ensure his death for an extended period of time.

1025. As applied in these circumstances and as written, the 2015 Execution Protocol creates, in the form of physical and mental agony, degradation, serious injury, and/or a lingering and spectacle of death, a significant risk of increased punishment as compared to the statute that first adopted lethal-injection as a method of execution in Ohio to which Plaintiff was originally subject.

1026. Plaintiff's death will be significantly more than quick and painless, a substantially greater punishment than that imposed by the statute that first adopted lethal-injection as a method of execution in Ohio to which Plaintiff was originally subject.

1027. Accordingly, the 2015 Execution Protocol is an unconstitutional ex post facto punishment, and thus invalid as written and as applied.

1028. In all the foregoing ways, Defendants violate Plaintiff's rights protected by the Ex Post Facto Clause of Article I, §§ 9 and 10 of the United States Constitution and 42 U.S.C. § 1983.

Eleventh Cause of Action: Bill of Attainders Violation

1029. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

1030. 01-COM-11, as applied in light of Ohio Revised Code § 2949.22(A), violates the Bill of Attainder Clause of Article I, Sections 9 and 10 of the federal Constitution.

1031. The punishment of death must be imposed, under Ohio law, "quickly and painlessly."

1032. A death sentence as carried out under the 2015 Execution Protocol implemented and administered by Defendants—employees and agents of an Ohio executive agency—will be neither quick nor painless.

1033. Thus, the physical pain, the mental anguish, the lingering death and the undignified spectacle execution to which Plaintiff will be subjected under the 2015 Execution Protocol will be elements of punishment inflicted on Plaintiff by some authority other than a judicial authority, namely by executive agency authority.

1034. Plaintiff, and other Ohio inmates sentenced to death, will be singled out for punishment at the hands of Defendants that will be neither quick nor painless.

Indeed, the recently passed HB 663 legislation was passed explicitly to intentionally ensure that Plaintiff and other Ohio death row inmates are executed as quickly as possible, with procedural restrictions put into place by that legislation to attempt to cover up and hide some of the information relevant to whether Plaintiff's execution is or will be quick or painless.

1035. Accordingly, the 2015 Execution Protocol and Defendants' informal execution procedures are an unconstitutional bill of attainder and invalid as written and as applied.

1036. In all the foregoing ways, Defendants violate Plaintiff's rights protected by the Bill of Attainder Clause of Article I, §§ 9 and 10 of the United States Constitution and 42 U.S.C. § 1983.

Twelfth Cause of Action: Eighth Amendment Violation—Deliberately Indifferent and/or Reckless Denial of Resuscitative Health Care After The Execution Is To Be Completed.

1037. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

1038. Under Defendants' Execution Protocol, Defendants will announce the point at which they believe the execution has been completed, *i.e.*, when Defendant Warden declares Plaintiff dead by announcing a time of death.

1039. There is a substantial risk, of which Defendants are aware but which they recklessly disregard and/or to which they are deliberately indifferent, that if Plaintiff is executed under Defendants' Execution Protocol he will not be clinically and statutorily dead when the execution has been declared completed.

1040. There is a substantial risk that Defendants will fail to plan, prepare for, or order medical treatment after heart and lung sounds are no longer detected and the inmate declared "dead" (and thus his death sentence completed), but when the inmate will still be alive and able to be resuscitated with proper medical care.

1041. Defendants have had ample time in advance of any execution and in advance of adopting the Execution Protocol to fully consider the substantial possibility that a condemned inmate will not be clinically and statutorily dead when the execution has been declared completed pursuant to the Execution Protocol, but have taken no corrective actions in that regard.

1042. A person's breathing and circulatory functions, and a person's brain stem functions, the irreversible cessation of which defines death under Ohio law, may be resuscitated through appropriate medical care for some period of time after receiving the execution drugs contemplated in Defendants' Execution Protocol.

1043. Upon information and belief, Defendants will not provide resuscitative care to Plaintiff after the time when his execution is concluded under Defendants' understanding of the Execution Protocol and its administration.

1044. Defendants know but recklessly disregard and/or are deliberately indifferent to the fact that their Execution Protocol contains no provisions for the appropriate medical care of an inmate whose sentence of death has been carried out, but who remains clinically and statutorily alive.

1045. Defendants make no provisions for emergency resuscitative care measures in the Death House, even after Defendants were put on notice of a significant risk of

problems in advance of an execution, such as occurred involving the lingering, spectacle execution of Dennis McGuire.

1046. Upon information and belief, Defendants are aware of the significant risk that problems may arise during an execution attempt, but they recklessly disregard and/or are deliberately indifferent to that risk by refusing to address the risk in their repeated revisions of the Execution Protocol.

1047. Upon information and belief, Defendants are aware of the significant risk that an inmate to whom they apply their Execution Protocol will remain clinically and statutorily alive even following completion of the Execution Protocol as to that inmate, and Defendants recklessly disregard and/or are deliberately indifferent to that risk because Defendants do not provide appropriate medical care to inmates whose sentences of death have been carried out in accordance with Defendants' Execution Protocol, even though they remain clinically and statutorily alive.

1048. Defendants' refusal to provide appropriate medical care to Plaintiff after he has been declared dead, but remains alive, constitutes deliberate indifference to unnecessary pain and suffering in violation of the Eighth and Fourteenth Amendments. *Estelle v. Gamble*, 429 U.S. 97, 104-05 (1976).

1049. The need to resuscitate Plaintiff, after his sentence has been completed but when he remains clinically and statutorily alive, is a serious medical need Defendants are constitutionally obligated under the Eighth Amendment to satisfy, but which they recklessly disregard and with deliberate indifference fail to satisfy, thereby violating Plaintiff's rights protected by the Eighth Amendment.

Thirteenth Cause of Action: Eighth Amendment Violation—Deliberate Indifference and/or Reckless Disregard Of Serious Medical Needs.

1050. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

1051. Under Defendants' Execution Protocol, controlled substances will be used to carry out a lethal-injection execution, namely pentobarbital and/or thiopental sodium.

1052. Dispensing a controlled substance such as pentobarbital or thiopental sodium requires a valid patient-specific prescription, which may only be issued under federal and state law for a legitimate medical purpose, in the best interests of the patient.

1053. Upon information and belief, one or more Defendants will issue an order to procure or dispense or distribute or administer execution drugs.

1054. Upon information and belief, Defendants know that a serious risk to Plaintiff's serious medical needs will arise if Defendants and any of them issue an order to procure or dispense or distribute or administer drugs that are specifically intended to kill Plaintiff by causing him to suffocate to death or by causing him a painful heart attack

1055. Defendants are deliberately indifferent to, and recklessly disregard, Plaintiff's serious medical needs when Defendants and any of them issue an order to procure or dispense or distribute or administer drugs that are specifically intended to kill Plaintiff by causing him to suffocate to death or by causing him a painful heart attack.

1056. Defendants and any of them are deliberately indifferent to, and recklessly disregard, the fact that such an order is not a valid order under federal and state law because the drugs will not be used to treat a legitimate medical need nor will they be used to protect the best interests of the patient.

1057. Defendants and any of them are deliberately indifferent to, and recklessly disregard, that issuing an order related to execution drugs that will be compounded creates a substantial risk that Plaintiff will experience severe harm, including torturous physical pain and/or mental suffering and agony.

1058. Defendants and any of them are deliberately indifferent to, and recklessly disregard, that issuing an order related to execution drugs that will be manufactured overseas and then illegally imported, i.e., smuggled, into Ohio creates a substantial risk that Plaintiff will experience severe harm, including torturous physical pain and/or mental suffering and agony.

1059. By facilitating procurement, dispensing, distribution or administration of execution drugs used to kill Plaintiff by issuing an order related to those drugs, Defendants and any of them who issues such an order demonstrates deliberate indifference and a reckless disregard for Plaintiff's serious medical needs, in violation of Plaintiff's Eighth Amendment rights. *Estelle v. Gamble*, 429 U.S. 97, 104 (1976).

Fourteenth Cause of Action: Fourteenth Amendment Due Process Clause Violation.

1060. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

1061. Plaintiff has a substantive due process right to "freedom from government actions that 'shock the conscience.'" *Range v. Douglas*, 763 F.3d 573, 588 (6th Cir. 2014) (quoting *Bell v. Ohio State Univ.*, 351 F.3d 240, 249-50 (6th Cir. 2003).

1062. Governmental action that is "arbitrary and capricious" is governmental action that is conscience-shocking. *Id.* (citations omitted).

1063. Governmental action that is in violation of state or federal law is the very definition of arbitrary and capricious.

1064. Accordingly, Plaintiff has a substantive right to be free from governmental action that is arbitrary and capricious because, among other things, it violates federal or state law.

1065. Defendants' Execution Protocol, as written and as applied, involves governmental action by Defendants that violates various state and federal laws related to drug products, and human experimentation, as identified throughout this Third Amended Omnibus Complaint, in the course of carrying out a punishment for Plaintiff's violation of the law.

1066. Defendants know of the violations of law that their Execution Protocol includes, and Defendants know of the violations of law that they commit or will commit in carrying out that Execution Protocol; for example, they know they will be violating the various federal and state drug laws, and that they will be violating the laws against non-consenting, involuntary human experimentation.

1067. Defendants know about but recklessly disregard and/or are deliberately indifferent to the numerous violations of state and federal law their Execution Protocol requires and that Defendants commit in carrying out an execution under the Execution Protocol.

1068. For instance, Defendants were on constructive notice regarding the prohibition on importing thiopental sodium to be used for a lethal-injection execution since the federal courts in 2012 and again in 2013 ordered FDA to seize and deny entry to the United States to any shipments of thiopental sodium.

1069. Defendants were on actual notice regarding the ban on importing thiopental sodium to be used for a lethal-injection execution for at least a year if not longer before they adopted their Execution Protocol.

1070. Nevertheless, upon information and belief, Defendants recently attempted to facilitate importing thiopental sodium to use for an execution under the Execution Protocol.

1071. Defendants have also been on notice for over a year that their intentions to obtain and use compounded sterile injectable controlled substances as execution drugs under the Execution Protocol are prohibited by various provisions of federal and state law.

1072. Nevertheless, upon information and belief, Defendants have attempted, and continue to attempt, to facilitate compounding pentobarbital or thiopental sodium to use for an execution under the Execution Protocol.

1073. Defendants have also been on notice for over a year that their Execution Protocol continues to constitute a human experimentation on an unwilling, non-consenting prisoner.

1074. Defendants have had ample time to fully consider the potential consequences of their conduct, but they chose to move forward with their current Execution Protocol nevertheless, and their repeated revisions of the Execution Protocol fail to even acknowledge the violations of law.

1075. Defendants are also aware of the facts that suggest a significant risk of harm to Plaintiff created by their use of pentobarbital or thiopental sodium as an execution drug, just as they were aware of the facts that suggested a significant risk of harm if they applied their previous execution protocol to Dennis McGuire.

1076. But Defendants recklessly disregard and/or are deliberately indifferent to these risks by retaining those drugs in their Execution Protocol and intending to use those drugs in an execution of Plaintiff.

1077. Defendants are also aware of the facts that suggest a significant risk of harm to Plaintiff created by their use of compounded execution drugs.

1078. But Defendants recklessly disregard and/or are deliberately indifferent to these risks by retaining those drugs in their Execution Protocol and pursuing those drugs to use in an execution of Plaintiff.

1079. Defendants are also aware of the facts that suggest a significant risk of harm to Plaintiff created by their use of imported execution drugs.

1080. But Defendants recklessly disregard and/or are deliberately indifferent to these risks by retaining those drugs in their Execution Protocol and pursuing those drugs to use in an execution of Plaintiff.

1081. For all of the foregoing reasons, Defendants' actions in recklessly and/or deliberately indifferently engaging in lawless behavior in pursuit of carrying out a punishment for breaking the law, and Defendants' actions in recklessly and/or deliberately indifferently attempting to obtain and use pentobarbital and/or thiopental sodium, including compounded or imported versions of those drugs, are arbitrary and capricious, they are shocking to the conscience, in violation of Plaintiff's rights protected by the substantive component of the Due Process Clause of the Fourteenth Amendment.

Fifteenth Cause of Action: Violation of Racketeer Influenced and Corrupt Organizations Act (RICO) alleged against Drug Source Defendants only

1082. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

A. Introduction

1083. Together with DRC defendants, Drug Source Defendants are part of a scheme to illegally obtain controlled substances and compounded drugs. This scheme violates numerous federal and state laws and those violations serve as predicate offenses under § 1961 of the RICO statute. Drug Source Defendants derive income from these racketeering activities in violation of § 1962(a). Plaintiff has been injured in his business or property by the reasons described in this cause of action. Federal courts have the jurisdiction under § 1964 to prevent and restrain RICO violations and Plaintiff asks for appropriate relief.

B. Predicate Acts under 18 U.S.C. § 1961(1)(A) (State law predicates)

1084. Under 18 U.S.C. § 1961(1), "racketeering activity" means (A) any act or threat involving . . . dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances Act), which is chargeable under State law and punishable by imprisonment for more than one year.

1085. Both pentobarbital and thiopental sodium are controlled substances under CSA.

1086. Under Ohio law, both pentobarbital and thiopental sodium are defined as "dangerous drugs." Ohio Rev. Code § 4729.01(F).

1. Retail sale and possession predicate

1087. Ohio law prohibits retail sales and possession of dangerous drugs for retail resale by anyone who is not a registered wholesale distributor of dangerous drugs or a licensed terminal distributor of dangerous drugs. Ohio Rev. Code § 4729.51(C)(1) and (2).

1088. Violation of Ohio Rev. Code § 4729.51(C)(1) and (2) is chargeable under State law as a felony. Ohio Rev. Code § 4729.99(E)(1) & (G).

1089. Upon information and belief, Drug Source Defendants either possess the lethal injection drugs with intent to resell to DRC Defendants or already sold DRC Defendants drugs in a retail sale in violation of Ohio Rev. Code § 4729.51.

1090. Specifically, Drug Source Defendants acting as importers purchased the drugs outside of the United States and are storing them for DRC Defendants, violating the "possession" provision of Ohio Rev. Code § 4729.51.

1091. Alternatively, Drug Source Defendants acting as intermediaries obtained the drugs from manufacturers, pharmacies, veterinarians, or other sources, and are storing them for DRC Defendants, violating "possession" provision of Ohio Rev. Code § 4729.51.

1092. Once the sale is complete and the DRC Defendants take possession of the drugs, Drug Source Defendants involved in the transaction violate the "retail sale" provision Ohio Rev. Code § 4729.51.

1093. By knowingly engaging in conduct that violates provisions of Ohio Rev. Code § 4729.51, Drug Source Defendants commit a felony under Ohio Rev. Code § 4729.99, and thus engage in racketeering activity under 18 U.S.C. § 1961(1)(A).

2. Compounding Pharmacists and Pharmacies predicate

1094. Under Ohio Rev. Code § 4729.99 (E)(1), violation of Ohio Rev. Code § 4723.37 is also a felony. This provision requires that prescriptions "may only be filled in accordance with the rules and regulations adopted by the state board of pharmacy."

1095. In turn, state board of pharmacy requires that for all sterile compounded prescriptions, the pharmacy shall comply with the United States Pharmacopeia (USP) chapter 797 and with section 503A of the Federal Food, Drug, and Cosmetic Act. Ohio Admin. Code 4729-16-03(B) & (C).

1096. Section 503A of the Federal Food, Drug, and Cosmetic Act is codified as 21 U.S.C. § 353a, likewise requires compliance with USP standards for compounded drugs. 21 U.S.C. § 353a(b)(1)(A)(i).

1097. USP Chapter 797 places responsibility on compounding personnel for ensuring that Compounded Sterile Preparations (CSPs) "are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed." USP on Compounding at 41. It mandates that "[c]ompounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their BUDs [beyond-use-dates] are reached or they are administered to patients." *Id.* at 66. It also demands that use and storage procedures, whether at compounding facility or in patient-care setting, must "include daily monitoring and documentation of drug storage refrigerators to ensure temperatures between 2° and 8° and the monthly inspection of all drug storage locations by compounding personnel." *Id.* at 67.

1098. USP Chapter <797> establishes three contamination categories for CSPs assigned primarily according to the potential for microbial contamination, which would subject

patients to risk of harm. *Id.* at 42. All compounded drugs that DRC Defendants intend to use fall into the high-risk category because they are compounded from nonsterile ingredients but must be made sterile before distribution. *Id.* at 44. USP Chapter <797> also sets special testing and procedural requirements for high-risk CSPs.

1099. Upon information and belief, Drug Source Defendants engaged in compounding and providing compounded drugs to DRC Defendants are violating USP provisions in the following manner:

a. by failing to follow verification procedures to check compounding accuracy and sterility, including testing for purity and sterility;

b. by failing to conduct and disclose the results of all testing required by USP Chapter 797 for high-risk CSPs;

c. by failing to follow and comply with all USP Chapter 797 provisions for high-risk CSPs;

d. by failing to ensure proper storage and security of CSPs prepared by them for DRC Defendants until their BUDs are reached or they are administered;

e. by failing to ensure that sterility, purity, and stability of CSPs is maintained during packaging, handling, and transport to DRC Defendants;

f. by failing to ensure that DRC Defendants implement appropriate operating procedures for storing and administering CSPs;

g. by failing to ensure that DRC Defendants implement and follow procedures specific to high-risk CSPs to comply with requirements of USP Chapter 797;

h. by failing to ascertain that DRC Defendants are able to store the CSPs properly, including the use of a properly functioning refrigerator and freezer if CSPs are labeled for such storage;

i. by failing to conduct daily monitoring and documentation and monthly inspection of locations where DRC Defendants are storing the compounded drugs and to guarantee that the CSPs are stored in proper conditions even at DRC facilities;

j. by failing to demand that outdated and unused CSPs be returned to the compounding facility for disposition;

k. by failing to provide appropriate education, training, and supervision to DRC defendants;

l. by failing to ensure that DRC Defendants use single-dose CSPs within 1 hour after initial needle puncture of the container and discard the rest;

1100. By failing to comply with USP mandates, those Drug Source Defendants engaged in compounding the drugs for use by DRC Defendants knowingly violate Ohio Admin. Code § 4729-16-03, compliance with which is required by Ohio Rev. Code § 4729.37, violation of which is a felony under Ohio Rev. Code § 4729.99(E)(1), and thus is a racketeering activity under 18 U.S.C. § 1961(1)(A).

3. Dispensing Pharmacist and Pharmacies predicate

1101. As discussed above, Ohio Rev. Code § 4729.37 requires that prescriptions "be filled in accordance with the rules and regulations adopted by the state board of pharmacy" and violation of this provision is a felony under Ohio Rev. Code § 4729.99(E)(1).

1102. State Board of Pharmacy required that "prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice." Ohio Admin. Code § 4729-5-21(A); § 4729-5-30. The Board places the responsibility on the pharmacists who dispenses the prescription. Ohio Admin. Code § 4729-5-30(A). It also provides that "[a]n order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law." *Id.*

1103. In addition, State Board of Pharmacy sets forth additional requirements for the manner in which the pharmacists must process a prescription in Ohio Admin. Code § 4729-5-21(A).

1104. Upon information and belief, Drug Source Defendants acting as either Dispensing or Compounding Pharmacists and Pharmacies, are violating Ohio laws by knowingly processing "prescriptions" for execution drugs in an unauthorized manner:

a. without a valid prescription, because an order for drugs from DRC Defendants using a death warrant is not "a prescription";

b. there is no legitimate medical purpose for the purported "order";

c. an order for execution drugs is not issued by an individual prescriber acting in the course of his or her professional practices.

1105. This felonious conduct described above constitutes racketeering activity within the meaning of 18 U.S.C. § 1961(1)(A).

C. Predicate Acts under 18 U.S.C. § 1961(1)(D) (federal law predicates)

1106. Under 18 U.S.C. § 1961(1), "racketeering activity" means (D) . . . the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances Act), punishable under any law of the United States.

1107. Both pentobarbital and thiopental sodium are controlled substances under the CSA.

1. Unlawful import predicate

1108. 21 U.S.C. § 959 prohibits procession, manufacture, or distribution of controlled substances, with punishment set forth in 21 U.S.C. § 960, which contemplates an enhanced sentence of not less than 20 years if death results from the use of the imported drug.

1109. Likewise, 21 U.S.C. § 957 prohibits import into the customs territory of the United States from any place outside thereof any controlled substance unless "there is in effect with respect to such person a registration issued by the Attorney General." Penalties for violation of this section are also set forth in 21 U.S.C. § 960 and also contemplate enhanced sentence of not less than 20 years if death results from the use of the imported drug.

1110. Finally, any person who attempts or conspires to commit any offense described in either § 957 or § 959 is subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

1111. Upon information and belief, Drug Source Defendants acting as importers are violating provisions of 21 U.S.C. § 957 by importing controlled substances into the United States without effectively registering with the Attorney General and while not exempt from such registration under the applicable statutory provisions.

1112. Upon information and belief, Drug Source Defendants acting as manufacturers, importers, or distributors of lethal injection drugs for DRC Defendants are violating 21 U.S.C. § 959(a) by manufacturing or distributing a Schedule II controlled substance intending or simply knowing that it will be unlawfully imported into the United States.

1113. Upon information and belief, Drug Source Defendants acting as distributors of lethal injection drugs for DRC Defendants are violating 21 U.S.C. § 959(b) by possessing a controlled substance when boarding an aircraft with intent to distribute these controlled substances to DRC defendants.

1114. Upon information and belief, Drug Source Defendants are violating are violating 21 U.S.C. § 963 by conspiring with DRC Defendants to import or distribute controlled substances into United States or by actually attempting to import or distribute controlled substances.

1115. Each of these felonious acts of manufacturing, importing, receiving, concealing, buying, selling, or otherwise dealing in a controlled substance constitutes racketeering activity under 18 U.S.C. § 1961(1)(D).

2. Unlawful Dispensing predicate

1116. 21 U.S.C. § 829 prohibits dispensing of Schedule II and III control substances without the written prescription of a practitioner.

1117. Penalties for violations of the dispensing statute are set forth in 21 U.S.C. § 841 et seq. and also contemplate enhanced sentence if death results from the use of the drug.

1118. Upon information and belief, Drug Source Defendants who are dispensing or compounding the drugs for use by DRC Defendants are doing so without a valid prescription.

1119. This felonious act of dealing in a controlled substance constitutes racketeering activity under 18 U.S.C. § 1961(1)(D).

3. Unlawful Compounding predicate

1120. Section 503A of the Federal Food, Drug, and Cosmetic Act is codified as 21 U.S.C. § 353a, requires compliance with USP standards for compounded drugs. Plaintiff incorporates by reference each and every statement and allegation related to USP violations enumerated above in Section B.2, Compounding Pharmacists and Pharmacies predicate, as if fully rewritten here. Knowing violations of USP

standards related to a controlled substance constitute racketeering activity under 18 U.S.C. § 1961(1)(D).

D. Other Predicates

1121. Plaintiff alleges other predicates based on violations of federal and state laws as described elsewhere in this Complaint, including violations of the federal FDCA, the federal CSA, the Ohio Pure Food and Drug Act, the Ohio Controlled Substances Act, the Ohio Pharmacy Practice Act, and others. Plaintiff reserves the right to add additional predicate acts upon further discovery.

E. Pattern of Activity

1122. Predicate Acts enumerated above are related by having the same purpose: delivering lethal injection drugs to DRC Defendants.

1123. Although methods used in obtaining these drugs may differ—whether obtaining them from compounding pharmacies or importing them from overseas—the goal of the scheme remains the same: to procure controlled substances and deliver them to DRC Defendants.

1124. This scheme is ongoing and continuing, because DRC Defendants have scheduled executions through May of 2019.

1125. Other States who execute their residents have contracted with entities engaged in a similar pattern of activity. At least four states bought the drug from a London-based company called Dream Pharma. Just last month, in August of 2015, Nebraska purchased sodium thiopental from a distributor in India, Chris Harris of HarrisPharma, Llp. At least one additional state and perhaps more—including, upon information and belief, DRC Defendants on behalf of the state of Ohio—have also

engaged HarrisPharma, Llp to obtain thiopental sodium to use for executions. And just recently, DRC Defendants received a warning letter from FDA that its plan to import drugs into the United States is illegal.

1126. Drug Source Defendants are willfully participating in the scheme to supply DRC Defendants with lethal injection drugs and are acting with full knowledge of illegality of their actions. Dream Pharma has shut down. The drugs purchased by Nebraska were returned by U.S. Customs and the Food and Drug Administration to the shipper in India used by HarrisPharma. Citing potential for legal concerns, the International Academy of Compounding Pharmacists issued a statement discouraging its members from participating in the preparation, dispensing, or distribution of compounded medications for use in executions. The American Pharmacists Association followed.

1127. Upon information and belief, driven by the demand from the DRC Defendants and lured by the profits, Drug Source Defendants will continue to engage in these racketeering activities.

F. Interstate and Foreign Commerce

1128. Drug Source Defendants are actively involved in interstate commerce by selling, transporting, producing, manufacturing, compounding, or receiving goods.

1129. All Defendants are using instrumentalities of interstate and foreign commerce such as mail, phone, Internet, and transportation.

G. Substantive RICO Violations under 18 U.S.C. § 1962

1130. Drug Source Defendants are deriving income from a pattern of racketeering activity as described above, in violation of 18 U.S.C. § 1962(a). Their income comes from illegally selling, transporting, distributing, compounding, dispensing, or otherwise

dealing in controlled substances destined for DRC Defendants to be used as execution drugs. Drug Source Defendants, whether individuals or business entities, are culpable persons within the meaning of 18 U.S.C. § 1961(2).

1131. Those Drug Source Defendants who are not individuals are business entities employing or associating with John Doe Defendants, and are enterprises within the meaning of 18 U.S.C. § 1961(4).

1132. John Doe Defendants are knowingly conducting or participating in the affairs of these enterprises through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

1133. Drug Source Defendants have conspired with DRC Defendants to derive income through the pattern of racketeering activity in violation of 18 U.S.C. § 1962(d).

H. Relief

1134. Plaintiff asks that the court prevent and restrain RICO violations by issuing appropriate orders, and for other relief, damages, and attorney's fees available under the RICO statute.

STATE LAW CLAIMS FOR RELIEF AGAINST DEFENDANTS

Sixteenth Cause of Action: Ohio Civil RICO claim against Drug Source Defendants

1135. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

1136. As described above in the Fifteenth Cause of Action under federal civil RICO laws, Drug Source Defendants and John Doe Defendants are engaged in conduct defined as racketeering activity under 18 U.S.C. 1961(1)(D).

1137. Engaging in, attempting to engage in, conspiring to engage in, or soliciting, coercing, or intimidating another person to engage this conduct also constitutes corrupt activity within the meaning of Ohio Revised Code § 2923.31(I).

1138. Those Drug Source Defendants who are not individuals are business entities employing or associating with John Doe Defendants, and are enterprises within the meaning of Ohio Revised Code § 2923.31(C).

1139. John Doe Defendants are knowingly conducting or participating in the affairs of these enterprises through a pattern of corrupt activity in violation of Ohio Revised Code § 2923.32(A)(1).

1140. Drug Source Defendants are knowingly receiving and using or investing proceeds from a pattern of corrupt activity as described above, in violation of Ohio Revised Code § 2923.32(A)(3).

1141. Drug Source Defendants engaging in the pattern of corrupt activity is likely to result in Plaintiff's death.

1142. Plaintiff thus brings this action under Ohio Revised Code § 2923.34(A) as an individual threatened with injury by a violation of § 2923.32 of the Ohio Revised Code.

1143. Plaintiff asks that under Ohio Revised Code § 2923.34(A)(2) the Court impose reasonable restrictions upon the future activities of Drug Source Defendants, including restrictions that prohibit them from engaging in corrupt activities.

1144. Plaintiff also asks the Court to grant injunctive relief pursuant to authority of Ohio Revised Code § 2923.34(D), which provides for injunctive relief "without a showing of special or irreparable injury."

Seventeenth Cause of Action: Claims for Declaratory Judgment Under Ohio Law Against All Defendants, and for Injunctive Relief Under Ohio Law Against Drug Source Defendants For Violations of Ohio Law.

A. Rights of Civil Action Under Ohio Law

1145. Under Ohio law, anyone subject to and injured by the criminal acts or activities of another has a right of a civil action against such person, including in respect to any, one or more of the Ohio crimes set forth at ¶¶ 567-577 above. *See* Ohio Rev. Code § 2307.60.

1146. Under Ohio law, a person has a right of civil action under the state RICO statute, Ohio Revised Code § 2923.34(A).

1147. Under Ohio law, a person has a right of a civil action in tort for negligence against a pharmacist or pharmacy that rises to negligence per se if that person shows damages, proximate cause and that the pharmacist or pharmacy violated any provision of the Ohio Pure Food and Drug Act, Ohio Revised Code § 3715 *et. seq*. *See Taugher v. Ling*, 127 Ohio St. 142, 146, syllabus paragraph 3 (1933) (holding that "[t]he Pure Food and Drug Laws of Ohio are statutes passed for the protection of the public, and a violation of them is negligence *per se*."); *Donley v. Pinnacle Foods Group, LLC*, No. 2:09-cv-540, 2010 U.S. Dist. LEXIS 25144, *3-4, 7-9 (S.D. Ohio Mar. 17, 2010).

1148. Ohio law permits Courts of Record to issue Declaratory Judgment to declare rights, status and other legal relations, whether or not further relief is or could be claimed. *See* Ohio Rev. Code § 2721.02(A). No action or proceeding is open to objection on the ground that a declaratory judgment or decree is prayed for under this chapter. *Id.* The declaration may be either affirmative or negative in form and effect. *Id.* The declaration has the effect of a final judgment or decree. *Id.*

1149. Ohio law enables Courts of Record to issue temporary orders restraining an act when it appears a person is entitled to the relief demanded, and such relief, or any part of it, consists in restraining the commission or continuance of such act, the commission or continuance of which, during the litigation, would produce great or irreparable injury to the plaintiff, or when, during the litigation, it appears that the defendant is doing, threatens or is about to do, or is procuring or permitting to be done, such act in violation of the person's rights respecting the subject of the action, and tending to render the judgment ineffectual. *See* Ohio Rev. Code § 2727.02.

B. Defendants' Violations of Ohio Laws

1150. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

1151. Rather than consider and heed the FDA's June 26, 2015 notice, information and explanation regarding sodium thiopental, or the *Beaty*/*Cook* rulings from 2012-2013, or information provided to them by Plaintiffs, the DRC Defendants issued their latest Execution Protocol on June 29, 2015 that formally stated Defendants would seek, manufacture, procure, acquire, produce, export, import, compound, supply, dispense, distribute, administer, provide, sell, deliver, offer for sale, hold for sale, and/or give away or otherwise source thiopental sodium to carry out a human execution by lethal injection.

1152. Rather than consider and heed information of which they were aware at the time, the DRC Defendants issued their latest Execution Protocol on June 29, 2015 that formally stated Defendants would seek, manufacture, procure, acquire, produce, export, import, compound, supply, dispense, distribute, administer, provide, sell,

deliver, offer for sale, hold for sale, and/or give away or otherwise source pentobarbital to carry out a human execution by lethal injection.

1153. By disregarding the FDA, the federal CSA, the federal FDCA, the Ohio Pure Food and Drug Act, the Ohio Controlled Substances Act, the Ohio Pharmacy Practice Act, and the various other Ohio statutory and regulatory provisions cited herein, Defendants have not just undertaken a course and conduct for violating federal law; Defendants have committed and are in continued process of committing crimes under the laws of the State of Ohio.

1154. Defendants or some number of them have undertaken a course and pattern and practice of conduct to engage in the violations of Ohio law identified elsewhere in this Third Amended Omnibus Complaint, as well as the following violations of Ohio law.

1155. Upon information and belief, Defendants Execution Team Members, none of whom qualify for the exception in § 2925.11(B)(1), will imminently violate Ohio Revised Code § 2925.11(A) by using on him a controlled substance—pentobarbital or thiopental sodium—without a lawful prescription issued by a licensed health professional authorized to prescribe drugs.

1156. Upon information and belief, Defendants or some number of them have violated or will imminently violate Ohio Revised Code § 2925.22(A), by illegally procuring the administration of, or the "prescription" of, or the dispensing of, dangerous drugs—namely thiopental sodium or pentobarbital—by deception, including, but not limited to, submitting false information in pursuit of a DEA license to import thiopental sodium; providing false or misleading paperwork to attempt to import thiopental

sodium into the United States; using a court order for execution to obtain or compound execution drugs rather than the required prescription that is valid under federal and state law.

1157. Upon information and belief, Defendants Execution Team Members, none of whom qualify for the exception in § 2925.02(B), will imminently violate Ohio Revised Code § 2925.02(A)(1) by using force, threat or deception to administer a controlled substance—namely pentobarbital or thiopental sodium—to Plaintiff, who will be strapped to a table and forcibly injected with the execution drug(s).

1158. Upon information and belief, Defendants Execution Team Members, none of whom qualify for the exception in § 2925.02(B), will imminently violate Ohio Revised Code § 2925.02(A)(3) by administering a controlled substance—namely pentobarbital or thiopental sodium—to Plaintiff and thereby cause him serious physical harm, including death.

1159. Upon information and belief, other Defendants who do not qualify for the exception in § 2925.02(B), will imminently violate Ohio Revised Code § 2925.02(A)(3) by furnishing a controlled substance—namely pentobarbital or thiopental sodium—to be administered to Plaintiff and thereby cause him serious physical harm, including death.

1160. Upon information and belief, Defendants Execution Team Members will imminently violate Ohio Revised Code § 2925.02(A)(2) by administering a controlled substance—namely pentobarbital or thiopental sodium—with the purpose to cause serious physical harm, including death, to Plaintiff.

1161. Upon information and belief, other Defendants will imminently violate Ohio Revised Code § 2925.02(A)(2) by furnishing, with the purpose to cause serious physical harm, including death, a controlled substance—namely pentobarbital or thiopental sodium—to be administered to Plaintiff.

1162. Upon information and belief, Defendants will imminently violate Ohio Revised Code § 2925.31(A), by obtaining, possessing and/or using on Plaintiff a harmful intoxicant—namely pentobarbital or thiopental sodium—with the purpose to induce in Plaintiff intoxication or similar physiological effects, other than for lawful research, clinical, medical, dental, or veterinary purposes.

1163. Upon information and belief, Defendants will imminently violate Ohio Revised Code § 2925.32(A)(1) by knowingly dispensing or distributing a harmful intoxicant (pentobarbital or thiopental sodium) to Plaintiff, who is over age 18, when Defendants know or have reason to believe that the pentobarbital or thiopental sodium will be used for the purpose of inducing in Plaintiff intoxication or similar physiological effects.

1164. Upon information and belief, Defendants will imminently violate Ohio Revised Code § 3715.65(A), by selling, delivering, offering for sale, holding for sale, and/or giving away a New Drug—namely thiopental sodium for any use, or pentobarbital to be used for a human execution—with respect to which there is no Investigational New Drug Application on file with FDA as required by 21 U.S.C. § 355 and which will be administered to Plaintiff to cause his death.

1165. Upon information and belief, Defendants will imminently violate Ohio Revised Code § 3715.52(A), by engaging in Prohibited Acts defined in that section, specifically

selling, delivering, offering for sale, holding for sale, and/or giving away pentobarbital or thiopental sodium that is adulterated and/or misbranded, § 3715.52(A)(1), to be used to cause Plaintiff's death.

1166. Upon information and belief, Defendants will imminently violate Ohio Revised Code § 3715.52(A), by engaging in Prohibited Acts defined in that section, specifically adulterating and/or misbranding the pentobarbital and/or thiopental sodium, § 3715.52(A)(2), that will be used to cause Plaintiff's death.

1167. Upon information and belief, Drug Supplier Defendants will imminently violate Ohio Revised Code § 3715.52(A), by engaging in Prohibited Acts defined in that section, specifically delivering or proffering delivery, for pay or otherwise, of adulterated and/or misbranded thiopental sodium or pentobarbital, § 3715.52(A)(3), to be used to cause Plaintiff's death.

1168. Upon information and belief, DRC Defendants will imminently violate Ohio Revised Code § 3715.52(A), by engaging in Prohibited Acts defined in that section, specifically receiving in commerce pentobarbital or thiopental sodium that is adulterated and/or misbranded, § 3715.52(A)(3), to be used to cause Plaintiff's death.

1169. Upon information and belief, Defendants Pharmacies #1-100 and Defendants Pharmacists # 1-100 are or will imminently engage in actions that amount to negligence per se because they are violating provisions of the Ohio Pure Food and Drug Act as identified herein to supply DRC Defendants with compounded pentobarbital or thiopental sodium that will be administered to Plaintiff and which may or will eventually kill him as a proximate result of being injected with those compounded drugs.

1170. Upon information and belief, Defendants or any of them have discussed, corresponded about, agreed, whether informally or formally or in principal or in contact, whether currently or for a future agreement, and contingently or otherwise, and taken steps to procure, manufacture, produce, export, import, compound, supply, distribute, provide, sell, deliver, offer for sale, hold for sale, and/or give away or otherwise source the drugs to be used to carry out a human execution under the Execution Protocol.

1171. Upon information and belief, DRC Defendants have or will imminently negligently fail to prevent or halt the commission of the crimes under Ohio law identified herein, in violation of Ohio Revised Code § 2921.44.

1172. Upon information and belief, DRC Defendants have or will imminently negligently fail to perform their lawful duties to carry out a quick and painless execution of Plaintiff, in violation of Ohio Revised Code § 2921.44.

1173. Upon information and belief, DRC Defendants have or will imminently recklessly fail to perform the duties expressly imposed by law with respect to their public servant's offices, such as duties related to carrying out Plaintiff's quick and painless lethal-injection execution in strict compliance with the Execution Protocol and all applicable federal and state policies, administrative regulations and statutes as identified herein. DRC Defendants know about, but recklessly disregard, the allegations of illegal activity alleged herein.

1174. Upon information and belief, Defendants have or will imminently perform acts with respect to carrying out a lethal-injection execution under the Execution Protocol that are expressly forbidden by law, as alleged herein.

1175. Just three days prior to DRC Defendants releasing their Execution Protocol, the FDA made it clear to Defendants, including Drug Source Defendants through DRC Defendants, that Defendants were without legal authority to issue or take action in reliance upon any instrument to engage in transactions for or relating to the importation of thiopental sodium into the United States.

1176. Drug Source Defendants have been on notice, constructive or actual, that Defendants were without legal authority to issue or take action in reliance upon any instrument to engage in transactions for or relating to the compounding of pentobarbital or thiopental sodium to use for an execution.

1177. In favor of the legally unauthorized Execution Protocol, Defendants—including Drug Source Defendants—have criminally and unlawfully cast aside the Ohio Revised Code's requirements and prohibitions identified herein. By doing so, Drug Source Defendants have undertaken to commit against Plaintiff various crimes identified and prohibited by Ohio law. *See* Ohio Rev. Code § 2921.52(B)(3)-(4).

1178. Pursuant to Ohio Revised Code § 2921.45, Defendants, under color of their office, employment, or authority, have undertaken to knowingly deprive, or conspire or attempt to deprive Plaintiff of a constitutional or statutory right, as alleged herein.

C. Relief

1179. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Third Amended Omnibus Complaint as if fully rewritten here.

1180. Pursuant to Ohio Revised Code § 2307.60, Plaintiff has the right to a civil action to recover from and against Defendants the full costs, attorney's fees and damages,

including, but not limited, to punitive damages, in respect to such actions of Defendants that are offenses against Plaintiff that are of a criminal nature.

1181. Pursuant to Ohio law, has a right to a civil action under the state RICO statute.

1182. Pursuant to Ohio law, Plaintiff has the right to a civil action in tort for negligence to recover from and against Defendants Pharmacies # 1-100 and Defendants Pharmacists # 1-100 for actions that are negligence per se because Defendants Pharmacies # 1-100 and Defendants Pharmacists # 1-100 have and will violate different provisions of the Ohio Pure Food and Drug Act, § 3715.01 *et seq.*, in the course of compounding and otherwise providing drugs to be administered to Plaintiff and that will kill him.

1183. Plaintiff does not bring either a civil cause of action under § 2307.60 or a civil tort claim in the above-captioned case against any of the Defendants. Rather, he seeks a declaratory judgment under Ohio Revised Code § 2721.02 to declare his and Defendants' rights, status and other legal relations—specifically a declaratory judgment that Defendants' actions violate the provisions of Ohio law as alleged herein, thus giving rise to Plaintiff's right to a civil cause of action under § 2307.60 and to a right to tort claims under Ohio law.

1184. Plaintiff also seeks injunctive relief as against the Drug Source Defendants. Plaintiff is not, however, seeking in this suit injunctive relief against DRC Defendants under Ohio law for violations of Ohio law.

1185. Defendants' actions in respect to Plaintiff's execution by lethal injection, identified in the preceding paragraphs, are offenses by Defendants against Plaintiff under Ohio law that are of a criminal nature.

1186. Defendants' actions against Plaintiff include those that have been and are without privilege and are wanton and malicious, reckless, and/or negligent.

1187. Upon information and belief, the danger of Defendants' violations of Ohio state laws as against Plaintiff are present, actual and genuine; DRC Defendants intend to execute him using the Execution Protocol and, in the process, to violate Ohio state law as alleged herein.

1188. Pursuant to Ohio Rev. Code § 2721.02(A), this Court has the authority to and should issue Declaratory Judgment for Plaintiff against Defendants, declaring that Defendants' actions and course of conduct to procure, manufacture, produce, process, export, import, compound, dispense, supply, use, administer, package, ship, store, sell, give away, offer for sale, or hold for sale pentobarbital, and Defendants' negligent, knowing, reckless, or wanton and malicious failures under the law associated with those efforts, constitutes one or more violations of Ohio law.

1189. Pursuant to Ohio Rev. Code § 2721.02(A), this Court has the authority to and should issue Declaratory Judgment for Plaintiff against Defendants, declaring that Defendants' actions and course of conduct to procure, manufacture, produce, process, export, import, compound, dispense, supply, use, administer, package, ship, store, sell, give away, offer for sale, or hold for sale thiopental sodium, and Defendants' negligent, knowing, reckless, or wanton and malicious failures under the law associated with those efforts, constitutes one or more violations of Ohio law.

1190. Pursuant to Ohio Rev. Code § 2727.02, this Court has the authority to and should issue temporary, preliminary and permanent injunctive relief in Plaintiff's favor

against Drug Source Defendants to restrain Drug Source Defendants' commission and continuance of violations of Ohio law against Plaintiff as alleged herein.

1191. Absent Plaintiff's receipt of such relief, Plaintiff would suffer great or irreparable harm as a result of Drug Source Defendants' many violations of Ohio state law, *see* Ohio Rev. Code § 2727.02, including violations of Plaintiff's rights as alleged in this Third Amended Omnibus Complaint and any Individual Supplemental Complaint as applicable, as well as death.

Eighteenth Cause of Action: Violation of Ohio Product Liability Act (Ohio Revised Code § 2307.71 et seq.)

1192. Pursuant to Ohio Rev. Code § 2307.71(A)(13), Ohio authorizes a"[p]roduct liability claim" to mean[] a claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following: (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product."

1193. Ohio Rev. Code 2307.74 defines defective in manufacture as "[a] product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards." Ohio Rev. Code § 2307.77 defines conformance to representation: "[a]product is defective if it did not

conform, when it left the control of its manufacturer, to a representation made by that manufacturer."

1194. Ohio Rev. Code § 2307.71(A)(9) defines manufacturer: ""Manufacturer" means a person engaged in a business to design, formulate, produce, create, make, construct, assemble, or rebuild a product or a component of a product."

1195. Ohio Rev. Code § 2307.71(A)(15) defines supplier: ""Supplier" means, subject to division (A)(15)(b) of this section, either of the following: (i) A person that, in the course of a business conducted for the purpose, sells, distributes, leases, prepares, blends, packages, labels, or otherwise participates in the placing of a product in the stream of commerce."

1196. Ohio Rev. Code § 2307.77 provides: "A product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation."

1197. 2307.78(A)(2) provides: "The product in question did not conform, when it left the control of the supplier in question, to a representation made by that supplier, and that representation and the failure to conform to it were a proximate cause of harm for which the claimant seeks to recover compensatory damages. A supplier is subject to liability for such a representation and the failure to conform to it even though the supplier did not act fraudulently, recklessly, or negligently in making the representation."

1198. Upon information and belief, Drug Source Defendants manufactured sodium thiopental and/or pentobarbital for sale to DRC Defendants for DRC Defendants' use to attempt to execute Plaintiff.

1199. Upon information and belief, Drug Source Defendants sold or attempted to sell sodium thiopental and/or pentobarbital to DRC Defendants for DRC Defendants' use to attempt to execute Plaintiff.

1200. Upon information and belief, Drug Source Defendants are either manufacturers of sodium thiopental and/or pentobarbital or they are suppliers of sodium thiopental and/or pentobarbital as defined in Ohio Rev. Code § 2307.71 or both.

1201. Upon information and belief, Drug Source Defendants misrepresented to DRC Defendants that the sodium thiopental and/or pentobarbital were manufactured to United States Pharmacopeia (USP) standards when indeed they were manufactured according to the lesser standards of the India Pharmacopeia (IP), the European Pharmacopeia (EUP, or the British Pharmacopeia (BP).

1202. Such deception as to the quality of the manufacturing process on the part of Drug Source Defendants as either manufacturers or suppliers constitutes a misrepresentation as to the products conforming to the standard of manufacture which renders the sodium thiopental and/or pentobarbital defective products under Ohio Rev. Code §§ 2307.77 and 2307.78(A)(2).

1203. As either manufacturers or suppliers or both, Drug Source Defendants are liable for compensatory damages arising from the use of this defective product. Plaintiff will be damaged by DRC Defendants' use of the defective products when DRC Defendants attempt to execute Plaintiff with a product that Drug Source Defendants

misrepresented to be of a different manufacture and quality than that which was sold to DRC Defendants.

1204. Plaintiff will experience severe, unnecessary, lingering, and inhumane pain and suffering from the defective sodium thiopental and/or pentobarbital manufactured or supplied by Drug Source Defendants.

1205. There is no practical method for Plaintiff to verify the quality, constitution, or uniformity of the sodium thiopental and/or pentobarbital prior to being subjected to their lethal injection.

1206. There exists a substantial, objectively intolerable risk that these drugs are the wrong identity or pH level, ineffective, sub-potent, contaminated, unsterile, or otherwise adulterated.

1207. Accordingly, and for all the reasons discussed in this petition, use of thiopental sodium and/or pentobarbital obtained from Drug Source Defendants creates substantial, objectively intolerable risk of DRC Defendants inflicting unnecessary pain, suffering, degradation, humiliation, and/or disgrace because on plaintiffs when DRC Defendants attempts to execute them with these drugs.

1208. Because there is no practical method to insure the purity of these defective drugs prior to their use, the use of any drugs manufactured or supplied by Drug Source Defendants must be permanently enjoined.

Nineteenth Cause of Action: Violation of Ohio Consumer Sales Practices Act (Ohio Revised Code § 1345.01 et seq.) Against Drug Source Defendants

1209. The Ohio Consumer Sales Practices Act (OCSPA) states in pertinent part:

> the act or practice of a supplier in representing any of the following is deceptive: [t]hat the subject of a consumer transaction has sponsorship, approval, performance characteristics, accessories, uses, or benefits that it does not have; [t]hat the subject of a consumer transaction is of a particular standard, quality, grade, style, prescription, or model, if it is not; and [t]hat the supplier has a sponsorship, approval, or affiliation that the supplier does not have.

Ohio Rev. Code §§ 1345.02(B)(1), (2), (9).

1210. A "consumer transaction" is defined as "a sale…or other transfer of an item or goods, a service, a franchise, or an intangible, to an individual for purposes that are primarily personal, family, or household, or solicitation to supply any of these things." Ohio Rev. Code § 1345.01(A). A "supplier" is defined as "a seller, lessor, assignor, franchisor, or other person engaged in the business of effecting or soliciting consumer transactions, whether or not the person deals directly with the consumer." Ohio Rev. Code § 1345.01(C).

1211. The goal of the OCSPA is to protect consumers. Therefore, it must be liberally construed in their favor. *Einhorn v. Ford Motor Co.*, 48 Ohio St. 3d 27, 29 (1990).

1212. In order "[t]o establish a prima facie claim under the OCSPA, a plaintiff must 'show a material misrepresentation, deceptive act or omission' that impacted his decision to purchase the item at issue." *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 798 (N.D. Ohio 2012) (citing *Temple v. Fleetwood Enters., Inc.*, 133 Fed. Appx. 254, 265 (6th Cir. 2006) (citations omitted)).

1213. Under the OCSPA, deception is measured from the standpoint of the consumer asserting the claim. *See Ferron v. Echostar Satellite, LLC*, 727 F. Supp. 2d 647 (S.D. Ohio 2009), *aff'd*, 410 Fed. Appx. 903 (6th Cir. 2010).

1214. "In order to be deceptive, and therefore actionable, a seller's act must not only be at variance with the truth but must also concern a matter that is or is likely to be material to a consumer's decision to purchase the product or service involved." *Richards v. Beechmont Volvo*, 127 Ohio App. 3d 188, 191 (1st Dist. 1998).

1215. A consumer does not, however, need to prove intent or scienter in order to prevail on a claim under the OCSPA. *Karst v. Goldberg*, 88 Ohio App. 3d 413, 417 (10th Dist. 1993).

1216. Upon information and belief, Drug Source Defendants have sold or attempted to sell to DRC Defendants sodium thiopental and/or pentobarbital manufactured in a foreign country, including but not limited to India.

1217. Under Ohio Rev. Code § 1345.01 this is a consumer transaction. Under Ohio Rev. Code 1345.01(C), Drug Source Defendants who have engaged in this activity are "suppliers" as they have sold or attempted to sell a product—thiopental sodium—to a consumer—DRC.

1218. Upon information and belief, Drug Source Defendants have deceived DRC in selling or attempting to sell DRC thiopental sodium and/or pentobarbital for use in Ohio executions.

1219. Upon information and belief Drug Source Defendants represented to DRC that the sodium thiopental and/or pentobarbital that Drug Source Defendants were to supply to DRC were manufactured according to USP standards.

1220. Upon information and belief, the sodium thiopental and/or pentobarbital that Drug Source Defendants were selling or offering to sell to DRC were or will be actually manufactured to the lesser standards of Indian Pharmacopeia (IP) or European Pharmacopeia (EUP) or British Pharmacopeia (BP).

1221. Upon information and belief, DRC purchased or attempted to purchase the sodium thiopental and/or pentobarbital based on the misrepresentations of Drug Source Defendants that the drugs were manufactured according to USP standards.

1222. Ohio Rev. Code § 1345.01(B)(2) prohibits a supplier from misrepresenting "[t]hat the subject of a consumer transaction is of a particular standard, quality, grade, style, prescription, or model, if it is not."

1223. Upon information and belief, Drug Source Defendants misrepresented the standard, quality , grade or prescription of the sodium thiopental and/or pentobarbital that they sold or attempted to sell to DRC in violation of Ohio Rev. Code § 1345.01(B)(2).

1224. Plaintiff here is the ultimate consumer of the product sold by Drug Source Defendants to DRC and will be the ultimate party to suffer from the misrepresentations of Drug Source Defendants, as he will be the one who will physically suffer when DRC Defendants use these drugs to attempt to execute Plaintiff.

1225. Upon information and belief, Drug Source Defendants misrepresent or misrepresented the purity of the sodium thiopental and/or pentobarbital to DRC yet the ultimate consumer who will be harmed by the impure drugs is Plaintiff.

1226. The deceptive misrepresentations of Drug Source Defendants in misrepresenting that the sodium thiopental and/or pentobarbital that they claim to be manufactured to USP standards when in reality they are not must be enjoined to prevent ongoing harm to

the ultimate consumers—Plaintiff, who will suffer when DRC Defendants attempt to execute him using impure execution drugs or drugs not manufactured to USP standards that were obtained from Drug Source Defendants.

1227. Ohio Rev. Code § 1345.09(D) provides: "Any consumer may seek a declaratory judgment, an injunction, or other appropriate relief against an act or practice that violates this chapter."

1228. Plaintiff therefore request that this Court enjoin Drug Source Defendants from misrepresenting the manufacturing standards for its drugs, and enjoin Drug Source Defendants from continuing to sell sodium thiopental and/or pentobarbital to DRC that is not manufactured to USP standards.

PRAYER FOR RELIEF

A. Plaintiff requests that this Court grant him injunctive relief under federal law in the form of the following:

a. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of their execution policy, including the Execution Protocol or any other execution policy, new or old, formal or informal which, as written or as administered, violates his federal constitutional rights;

b. preliminary and permanent mandatory injunctions requiring Defendants to adopt, and adhere in their administration to, a facially constitutional written execution protocol in efforts to execute him, and that such written execution protocol must formally adopt the Incident Command Systems principles and application in the execution context as a formal element of Defendants' written execution protocol;

c. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of their execution policy, including the Execution Protocol or any other execution policy, new or old, formal and/or informal that is facially unconstitutional, including facial unconstitutionality for failure to ensure that an unconstitutional execution is not carried out;

d. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of an execution policy, including the Execution Protocol or any other execution policy, new or old, formal and/or informal, that is unconstitutional as applied to him, including as-applied unconstitutionality for failure to ensure that an unconstitutional execution is not carried out;

e. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of an execution policy, including the Execution Protocol or any other execution policy, new or old, formal or informal, that involves or allows any use of execution drugs manufactured by compounding or using compounding methods, or that involves or allows any use of pharmacists or pharmacies to manufacture the execution drug(s) via compounding, or that involves or allows any use of execution drugs manufactured by any pharmacist or pharmacy;

f. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of an execution policy, including the 2015 Execution Protocol or any other execution policy, new or old, formal and/or informal, that involves or allows any use of execution drugs manufactured by compounding or using compounding methods, or that involves or allows any use of pharmacists or pharmacies to manufacture the execution drug(s) via compounding, or that involves or allows any use of execution drugs manufactured by any pharmacist or pharmacy when such pharmacist and the relevant drug-making facility has not been formally inspected, vetted, investigated, verified, and passed all such inquiries;

g. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of an execution policy, including the 2015 Execution Protocol or any other execution policy, new or old, formal and/or informal, that involves or allows any use of execution drugs manufactured by compounding or using compounding methods, or that involves or allows any use of pharmacists or

pharmacies to manufacture the execution drug(s) via compounding, or that involves or allows any use of execution drugs manufactured by any pharmacist or pharmacy, when such drugs and Defendants' related actions have not been, before use in any execution, inspected, tested and analyzed by an independent entity approved by Plaintiff, to ensure that the drugs are pure, unadulterated, uncontaminated, not expired or beyond-use-date, of the exact type, potency, and concentration, not imported (including not manufactured using imported raw API), and not manufactured, prepared, mixed, assembled, labeled, packaged, stored, transferred, distributed, acquired, or any other such matter, in a way that violates any federal or State of Ohio laws;

h. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of their execution policy and written execution protocol to which they have failed to strictly adhere;

i. preliminary and permanent prohibitory injunctions barring Defendants from executing him by a means that will deny his liberty, life, and property interests in the expectation and receipt of a quick, painless, humane and dignified death, which interests are guaranteed by Ohio Rev. Code § 2949.22(A) and DRC Policy 01-COM-11 and protected by the substantive and procedural elements of the Due Process Clause of the federal constitution's Fourteenth Amendment;

j. preliminary and permanent prohibitory injunctions barring Defendants from execution him by a means that will deny any other fundamental rights as alleged herein;

k. preliminary and permanent mandatory injunctions requiring Defendants to comply with all training and Execution Team personnel requirements set forth in the written execution protocol, and prohibiting supervisory personnel from allowing Execution Team member participation in any execution without full compliance with all of the written protocol's substantive training requirements, execution rehearsal training requirements, and other mandatory provisions;

l. preliminary and permanent prohibitive injunctions preventing Defendants from enforcing those provisions of their execution policy and written execution protocol that violate Plaintiff's First Amendment rights to free speech;

m. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of an execution policy, including the 2015 Execution Protocol or any other execution policy, new or old, formal and/or informal, that fails to ensure and protect his Due Process right to know, well in advance, the method of execution by which Defendants will attempt to execute him; the source of the drug(s) with which Defendants will attempt to execute him; all relevant information regarding the involvement of any Drug Source Defendants; whether the drug(s) to be used to execute him are pure, unadulterated, uncontaminated, not expired/beyond their labeled use date, of the exact type, potency, and concentration, not imported (including not manufactured using imported raw API), and not manufactured, prepared, mixed, assembled, labeled, packaged, stored, transferred, distributed, acquired, or any other such matter, in a way that violates any federal or State of Ohio laws;

n. preliminary and permanent prohibitive injunctions preventing Defendants from attempting to conduct any further executions until such time as the Court orders otherwise;

o. preliminary and permanent injunctions prohibiting Drug Source Defendants from supplying DRC Defendants with drugs that do not comply with all federal and state law

p. Preliminary and permanent injunctions prohibiting Drug Source Defendants from engaging in actions that violate federal and Ohio state law.

B. Plaintiff requests that this Court grant him declaratory relief under federal law in the form of the following:

a. an Order declaring that Defendants' execution policy and written execution protocol will subject him to a substantial risk of harm, including severe physical and/or psychological pain, needless suffering, and a torturous, lingering, undignified, and/or spectacle execution or attempted execution, and/or an objectively intolerable risk of such harm that Defendants unjustifiably ignore, resulting in cruel and unusual punishment, whether that method is through the policy's Plan 1 or Plan 2, and that Defendants' execution policy and written execution protocol fails to ensure against an execution that would constitute cruel and unusual punishment, and will thus violate Plaintiff's rights under the Eighth and Fourteenth Amendments to the United States Constitution;

b. an Order declaring that Defendants' substantial, documented and admitted deviations and/or pattern of deviations and/or variations from their written execution protocol and the safeguards contained therein, as applied in Defendants' execution policy before, during and after administration of the execution policy, creates a substantial risk of harm, including severe physical and/or psychological pain, needless suffering, and a torturous, lingering, undignified, and/or spectacle execution or attempted execution, and/or an objectively intolerable risk of such harm that Defendants unjustifiably ignore, in violation of Plaintiff's rights under the Eighth and Fourteenth Amendments;

c. an Order declaring that Defendants' execution policy and written execution protocol denies his life, liberty and property interests in expecting and receiving a quick, painless, humane and dignified death, which interests are created under binding state law in the form of Ohio Revised Code § 2949.22 and/or DRC Policy 01-COM-11, and protected as rights by the substantive and procedural elements of the Fourteenth Amendment's Due Process Clause, resulting in denial of his substantive and procedural due process rights;

d. an Order declaring that Defendants' execution policy, their written execution protocol and Ohio Revised Code § 2949.25(A) as applied and Ohio Rev. Code § 2949.25(A)(5) as written and applied impermissibly condition, restrict and/or deny Plaintiff the unhindered right to have his counsel present to witness Phillips's execution, and to represent Plaintiff's interests;

e. an Order declaring that Defendants' substantial and demonstrated deviations and/or pattern of deviations and/or variations from their execution policy and

written execution protocol before, during and after administration of the policy and protocol is not necessary to achieve any compelling state interest, and that such deviations and/or variations substantially burden the fundamental rights of the class of persons of condemned inmates subject to a death sentence imposed in Ohio state courts—which includes Plaintiff—under the First, Sixth, Eighth, Ninth and Fourteenth Amendments, in violation of his rights to equal protection under the Fourteenth Amendment to the United States Constitution;

f. an Order declaring that Defendants' substantial and demonstrated deviations and/or pattern of deviations and/or variations from their execution policy and written execution protocol before, during and after administration of the policy and protocol, is unrelated to any legitimate governmental interest, and arbitrarily and irrationally treats or will treat Plaintiff as a class of one differently than others similarly situated, in violation of his rights to equal protection under the Fourteenth Amendment to the United States Constitution;

g. an Order declaring that Defendants' execution policy and written execution protocol facially violates Plaintiff's rights protected by the Fourteenth Amendment's Equal Protection Clause because it allows Defendants to treat similarly situated individuals differently, such disparate treatment burdens the fundamental rights of the class of persons of condemned inmates subject to a death sentence imposed in Ohio state courts—which includes Plaintiff—under the First, Sixth, Eighth, Ninth and Fourteenth Amendments, and it is not necessary to achieve a compelling state interest;

h. an Order declaring that Defendants' execution policy and written execution protocol facially violates Plaintiff's rights as a class of one protected by the Fourteenth Amendment's Equal Protection Clause because it allows Defendants to treat Plaintiff different than similarly situated individuals, without any legitimate governmental interest, irrationally and arbitrarily;

i. an Order declaring that he and other condemned inmates have fundamental, unenumerated rights that arise under the principles of liberty and natural law, which rights are protected by the Ninth Amendment to the United States Constitution, and that Defendants' execution policy and written execution protocol, as written and as applied, violates those fundamental rights in violation of the Ninth Amendment;

j. an Order declaring that he and other condemned inmates have a fundamental right against being forced to be an unwilling, non-consenting subject of human experimentation that is guaranteed by the fact of their status as United States citizens and protected by the Privileges or Immunities Clause of the Fourteenth Amendment, and that Defendants' Execution Protocol, as written and as applied, violates that fundamental right;

k. an Order declaring that those portions of Defendants' execution policy and written execution protocol that provide discretion to governmental actors to impose restrictions on the content and length of any last statement given before an execution attempt are, facially and as applied, impermissible content-based restrictions, and/or violations of the public forum and/or limited public forum

doctrines, and therefore in violation of Plaintiff's rights to free speech under the First Amendment;

l. An Order declaring that Plaintiff's right to due process requires that Defendants notify him no less than 30 days before his scheduled execution of: which method of execution Defendants will use; whether Defendants will use execution drugs manufactured by compounding methods and/or manufactured by a pharmacist or pharmacy; which pharmacist will make the execution drug(s) to be used for his execution; and all other relevant information;

m. An Order requiring full testing, investigation, analysis, and inspection related to any compounded execution drug(s) and any Drug Source Defendants and his/her manufacturing facility to be involved in any way related to an execution in Ohio, to be done by an independent party not affiliated or connected or related in any way to the government of the State of Ohio or any Defendants or their agents under 01-COM-11;

n. An Order declaring that the reasoning and analysis in any prospective opinion issued by this Court temporarily and preliminarily enjoining Defendants from executing him applies to preclude Defendants from attempting any further executions until such time as the Court orders otherwise.

o. Such other declaratory relief as Plaintiff may subsequently request.

C. Plaintiff requests that this Court grant him declaratory relief under Ohio state law in the form of declaration that Defendants' actions related to execution drugs are violating or will violate federal and state statutes and administrative regulations.

D. Plaintiff requests that this Court grant such further as otherwise requested herein.

E. Plaintiff requests that this Court grant such further relief as it deems just and proper.

F. Plaintiff requests that this Court grant him reasonable attorney fees under 42 U.S.C. § 1988 and the laws of the United States, as applicable.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff demands a trial by jury of all issues so triable.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 24, 2015, the foregoing **THIRD AMENDED COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF, ATTORNEY FEES AND COSTS OF SUIT PURSUANT TO 42 U.S.C. § 1983 AND OTHER RELATED CAUSES OF ACTION** was filed electronically with the Clerk of the United States District Court for the Southern District of Ohio using the CM/ECF system, which will send notification of such filing to the following opposing counsel at the e-mail address on file with the Court:

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